

**A STUDY ON PREVALENCE OF PSYCHIATRIC
CO-MORBIDITY, ALCOHOL ABUSE, PERSONALITY
FACTORS IN TUBERCULOSIS DEFAULT PATIENTS**

*Dissertation submitted for partial fulfillment of the
rules and regulations*

**DOCTOR OF MEDICINE
BRANCH - XVIII (PSYCHIATRY)**



THE TAMILNADU DR.MGR MEDICAL UNIVERSITY

CHENNAI.

TAMIL NADU

MAY 2018

CERTIFICATE

This is to certify that the dissertation titled, “**A STUDY ON PREVALENCE OF PSYCHIATRIC CO-MORBIDITY, ALCOHOL ABUSE, PERSONALITY FACTORS IN TUBERCULOSIS DEFAULT PATIENTS**” is the bonafide work of **Dr. VISHNUPRIYA.V.**, submitted in partial fulfilment of the requirements for M.D. Branch-XVIII [Psychiatry] examination of The Tamilnadu Dr. M.G.R. Medical University, to be held in may 2018.

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CERTIFICATE OF GUIDE

This is to certify that the dissertation titled, **“A STUDY ON PREVALENCE OF PSYCHIATRIC CO-MORBIDITY, ALCOHOL ABUSE, PERSONALITY FACTORS IN TUBERCULOSIS DEFAULT PATIENTS”** is the bonafide work of **Dr. VISHNUPRIYA.V.**, done under my guidance submitted in partial fulfilment of the requirements for M.D. Branch - XVIII [Psychiatry] examination of The Tamil Nadu Dr. M.G.R. Medical University, to be held in may 2018.

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DECLARATION

I, **Dr. VISHNUPRIYA.V**, solemnly declare that the dissertation titled, **“A STUDY ON PREVALENCE OF PSYCHIATRIC CO-MORBIDITY, ALCOHOL ABUSE, PERSONALITY FACTORS IN TUBERCULOSIS DEFAULT PATIENTS”** is a bonafide work done by me at the Institute of Mental Health, Chennai, during the period from March 2017 – May 2017 under the guidance and supervision of **Dr. A. SHANTHI NAMBI**. Professor of psychiatry, Madras Medical College.

The dissertation is submitted to the The Tamilnadu Dr. M.G.R. Medical University towards partial fulfilment of requirement for M.D. Branch XVIII [Psychiatry] examination.

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**INSTITUTIONAL ETHICS COMMITTEE
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Dear Dr.V.Vishnupriya,

The Institutional Ethics Committee has considered your request and approved your study titled **"A STUDY ON PREVALENCE OF PSYCHIATRIC CO-MORBIDITY , ALCOHOL ABUSE, PERSONALITY FACTORS IN TUBERCULOSIS DEFAULT PATIENTS" - NO.11012017 (III).**

The following members of Ethics Committee were present in the meeting hold on **24.01.2017** conducted at Madras Medical College, Chennai 3

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We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

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ABBREVIATIONS

AUDIT	-	Alcohol Use Disorders Identification Test
ADS	-	Alcohol Dependence Syndrome
YMRS	-	Young Mania Rating Scale
HAMD	-	Hamilton Depression Rating Scale
ADS	-	Alcohol Dependence Syndrome
RNTCP	-	Revised National Tuberculosis Control Programme
WHO	-	World Health Organisation
HIV	-	Human Immunodeficiency Virus
TB	-	Tuberculosis
MDR	-	Multi Drug Resistant
DOTS	-	Direct Observed Treatment Shortcourse
ICD	-	International Statistical Classification of Diseases and Related Health Problems
CNS	-	Central Nervous System

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INTRODUCTION

Tuberculosis is a chronic debilitating infectious disease which has a high morbidity and mortality. Center for disease control and prevention says that “about one-third of the world’s population is infected with tuberculosis”. In 2015, 10.4 million people around the world were found to be sick with tuberculosis and there were 1.8 million tuberculosis related death due to unawareness regarding treatment, 50-65% of the patients died within a year (Fauci A, Kasper D, Braunwald E 2008)² In India, nearly 1.98 million new cases reported every year which constitute nearly 20% of the global total tuberculosis disease burden. RNTCP in India is declared as the second largest in the world (Moharani et al)¹⁹. Non adherence is one of the main drawbacks in the management of this disease because tuberculosis patients expected to have adherence greater than 90% for cure (Harries A, Maher D, Graham S (2004)^{3,4}.

WHO definitions and reporting framework for tuberculosis -2013 revision says that, “a tuberculosis patient whose treatment was interrupted for 2 consecutive months or more is known as lost to follow up and treatment after default is currently termed as treatment after lost to follow up”. Factors like forgetfulness, being in the continuation phase of the treatment, feeling better with the drugs, co-morbid HIV infections, poor understanding about the illness, concluding that tuberculosis is a mere physical illness or incurable one were found to be the reasons for non-adherence in studies conducted in developing countries (Sardar P et al, Akilew Avoke Adane et al, Sudhir et al)^{5, 6, 20} Other factors like type of housing in which people reside, overcrowding,

homelessness are also been proved as cause for non adherence as per Garfein et al 2010²¹

Studies have shown high prevalence of depression, generalized anxiety disorders, adjustment disorders in patients with tuberculosis (Westaway et al 1992, Aghanwa et al 1998)^{1, 7}

Low self esteem, fear of spreading the illness to others, helplessness brought out by incapacitation due to chronic illness, and social stigma associated with the illness, are all causes that one can postulate for depression and anxiety (Argiro et al 2013)¹⁷. After knowing the diagnosis of tuberculosis, patients tend to have mixed feelings of loneliness, depression, suicidal thoughts, fear, apathy, surprise and acceptance due to the stigma (Argiro et al 2013)¹⁷ Prevalence of depression was 27% according to previous studies⁹ (Baba et al 1985) and Indian studies (Natani et al)¹⁰ have shown prevalence is 49%

Alcoholism and other drug addiction also play a role in poor drug adherence (Rose N et al 1991)⁸ Alcohol can directly cause a person to default from treatment and a delay in the diagnosis of tuberculosis was also associated with alcoholism (Brian Lacky et al)^{11,19} Previous studies show that heavy drinkers also have serious forms of tuberculosis, high chances of default, relapse and continue to be infectious to others, at high risk for premature death posing serious public health concerns (Jianzhao H et al 2011, Finlay A et al 2002, Vree M et al 2007)^{12,13,14} Unsuccessful outcome like relapse and default

are high among patients who consumed alcohol during the course of treatment as the bacteria is mainly destroyed by alveolar macrophages and alcohol will promote intracellular survival of mycobacterium by suppressing phagocytosis and impairs the immune system responses against tuberculosis¹⁸. The need for a pre-treatment psychological assessment for screening of alcohol use disorders have been highlighted by Karthikeyan et al¹⁸ study 2014. Detecting alcohol use disorders like abuse and dependence helps in early intervention effects to prevent the adverse impacts of consumption.¹⁹

Previous studies have described the personality of tuberculosis patients as “childish, self-centered, irritable, dissatisfied with life” (Jelliffe et al 1919)¹⁵ Many patients who suddenly discontinue the treatment in a sanatorium and go for default were mainly found to have chronic alcoholism (Ashmore et al 1943)¹⁶ Patients found to be mostly associated with poor drug adherence and default mainly had neurotic traits, were submissive, emotional labile and over protective and behavioral modification by psychotherapy for neurotic traits proved to be effective in prevention of default as per studies done by Sudhir choudary et al²⁰

As per Bergman, Haley, and Small²² (2011) mental variables or health beliefs such as attitude, values and knowledge about health and health service also decide drug adherence. Psychological distress is defined as “state of mind where the emotional suffering is associated with depression and anxiety” (Drapeau et al., 2011; Vidyulatha Peddireddy, 2016)^{24,28} High levels of psychological stress, adverse life events were associated with tuberculosis

(Geldenhuys et al., 2011)²⁵ which produced a negative impact on the treatment adherence. Studies also insist the need for psychological interventions in individuals with chronic illness as they may indulge in risk taking behavior which adversely affects the treatment outcome. Patients with psychological distress tend to die before 25yrs when compared with general population (NASMHPD, 2006)²⁶ and have very poorer quality of life (Veggi et al., 2004)²⁷. Psychological distress in tuberculosis patients and the need for psychological intervention is still under-studied among Indian population as per Vidyulatha Pedireddy, 2016²⁸

Social stigma which is defined 'āsān undesirable or discrediting attribute that an individual possesses, thus reducing that individual's status in the eyes of society place a vital role in the management of chronic illness like tuberculosis as well as psychiatric illness" (Gofmann et al 1963)²³ In India, stigma was more prevalent among women (Dhingra and Khan, 2010)²⁹. In a study that recruited TB patients from South India, it was observed that distress and anxiety was observed in about 50% of the study subjects when disclosed about the diagnosis and about 9% of them attempted suicide (Rajeswari et al., 2005)³⁰ Among Indian population, studies say that psychological reaction was severe, when patients were informed about the diagnosis of TB and the main worries were mainly about the deadliness of the disease, treatment options, embarrassment, social stigma and the feeling that fate was not kind to them (Thakker et al., 2014) ³¹Psychological intervention improved the patients' treatment compliance, outcome and levels of CD4+T lymphocytes (Wei et al

2016)³² But the studies highlighting the role of psychological factors including psychiatric illness is very meager in Indian population²⁸

In Tamil Nadu, the default rate was 20% which was more than twice as that of the national average and the main causes were stated as alcoholism, warranting the need for motivation strategies to enhance drug adherence (Jaggarajamma et al)³³ Failure rates in Tamil Nadu was found to be 13. 2% where north of India reported failure rates of 7% (Pauline et al 2011³⁴, Singla et al 2009)³⁵

Prior studies show that in Tamil Nadu, depression was nearly 42% among tuberculosis patients and being old, married, educated, female and higher income group were found to have lower incidence of depression (Francis et al 2017)³⁶ About 29% of tuberculosis patients abused alcohol and among them nearly 52% had a AUDIT score>8 which actually signifies hazardous, harmful and dependent drinking (Beena Thomas et al)³⁷

Heavy drinkers face the dual stigma of alcoholism and tuberculosis and among tuberculosis defaulter patients 47% were heavy drinkers and odds ratio was 3. 8% for heavy drinkers when compared with other causes of default (Jabuboviak et al, Jaggarajamma et al, De Albuquerque et al)^{38,33,39}

The fear of the adverse effects of TB drugs and alcohol, the fear of the reduction in the therapeutic effect of the drugs when alcohol is consumed and the fears of being reprimanded by health providers when they report to the clinic with an odor of alcohol are the adverse factors associated with the drug

adherence which leads to default (Beena Thomas et al)³⁷ and this study conducted in Tamil Nadu also highlight the need for the involvement of family members in intervention programs.

Studies recognize the need to screen TB patients for alcohol use and encourage abstinence, targets risky alcohol users, including those in alcohol treatment programs to enhance TB screening as per Government of India RNTCP training module 2014⁴⁰

Studies identifying prevalence of psychiatric illness, alcoholism and personality factors is very meager. India has a high burden of tuberculosis, along with psychiatric illness faces heavy stigma and has got grave effect on outcome of both illness. This study is an effort in that direction.

REVIEW OF LITERATURE

LOST TO FOLLOW UP

Tuberculosis patients lost to follow-up (LTFU) are defined as “Tuberculosis patients who did not start treatment or whose treatment was interrupted for two consecutive months or more” and were previously called defaulters⁴¹. LTFU patients are more likely to redevelop infectious active TB, and are found at a higher risk of developing MDR-Tb (Caminero et al 2010)⁴² Lost to follow up occurred more often in the continuation phase (58. 8%) than in the intensive phase of treatment (34. 2%) (Jessica et al)⁴³

People living with TB and mental illness are at greater risk of poor health-seeking behaviour, and poor medication adherence with consequent adverse treatment outcomes including morbidity, mortality, drug-resistance and ongoing disease (Sweetland et al 2014)⁴⁴ Prevalence of psychiatric co-morbidity was found to be nearly 70% as per Doherty et al 2013⁴⁵ and was associated with high levels of social disability, social stigma, poor social support and physiological disturbances (Aydin et al⁴⁶ and Pachi et al¹⁷) Tuberculosis and psychiatric illness share common risk factors like poverty, substance abuse and homelessness (Doherty et al 2013)⁴⁵

PSYCHIATRIC DISORDERS AND TUBERCULOSIS:

Mental disorders make a substantial independent contribution to the burden of disease worldwide (Baxter et al)⁴⁷ Common mental disorders (CMDs) are characterized by a broad range of depressive, anxiety or somatoform symptoms, including irritability, insomnia, nervousness, fatigue and feelings of uselessness (Fonseca et al)⁴⁸ In developing countries, the prevalence of Common mental disorders varies between 20%–30% (Patel et al 2003)⁴⁹ Psychiatric illness have a chronic and disabling nature, cause intense subjective suffering and affect individuals' abilities to care for their own health (Fonseca et al⁴⁸, Veggi et al²⁷)

“Reduction in vital energy” and “depressive thoughts” reflect individual stressors; stress can mediate the relationship between psychosocial problems and physical illness, as stress has an effect on the bacterial load in the lungs and the immune defense system (Stein et al⁵⁰, Schneiderman et al)⁵¹

Few studies which tried to establish a relationship between psychiatric illness and tuberculosis have highlighted the effects of stress on immune functioning and the progression from infection to disease and also that the diagnosis of tuberculosis increases risk of mental illness (Doherty et al⁴⁵, Balaji et al⁵², Bender et al⁵³) The association between psychiatric illness and tuberculosis contributes to the inadequate adherence to the proposed treatments and aggravates the clinical description of both diseases (Pachi et al¹⁷, Prince et al⁵⁴)

Tuberculosis can be wrongly diagnosed as a common mental disorder in mental health clinics and might raise the public health costs unnecessarily (Pachi et al¹⁷, Deribew et al⁵⁵) Hence the need for inclusion of mental health program integrated within tuberculosis control program suggested by Gleide Sandos et al 2014⁵⁶

RELATIONSHIP BETWEEN PSYCHIATRIC ILLNESS AND TUBERCULOSIS:

McQuiston et al 1997⁵⁷ has found that 30% of patients with depressive illness and 14% with psychotic illness have a positive PPD (Purified Protein Derivative) results. Lopez et al⁵⁸ gives 19% prevalence for PPD admissions to a psychiatric unit. Saez et al⁵⁹ (1975) gives 36.7% of men in a homeless hostel with mental illness showed a positive PPD results.

Psychiatric patients also have risk factors like poor nutrition, smoking, diabetes mellitus which results in the progression from latent to active tuberculosis as per Doherty et al⁴⁵ (2013)

Chronic medical illness are commonly associated with psychiatric illness like depression (Moffic et al)⁶⁰ and Aghanwa et al⁷ says that rate is twice than in orthopedic patients but less than chronic respiratory illness as per Moussas et al⁶¹

Non-compliance with the treatment resulting in MDR-tuberculosis was found to be associated with psychotic disorders and substance abuse as per LaRaja et al⁶² (1997) Number of strategies which have been suggested to

overcome this problem of non-compliance including residential treatment, and even isolation of patients with mental illness and co-morbid tuberculosis, resulted in increase the individual's stress levels (Westaway et al 1992)¹

Among opioid-dependent patients, when direct observation treatment was combined with methadone maintenance therapy, outcome was good as per Bhatki et al⁶³ Chronic respiratory illness was associated with increased risk of suicide (Horton et al 1992)⁶⁴ Wagenlaher et al⁶⁵ (2006) described a case of psychosis secondary to milliary tuberculosis with significant involvement of the urinary tract at initial presentation.

Panic disorder was found to be secondary to tuberculous meningitis, and a case of frontal tuberculoma presenting as a postnatal depression has been reported (Chand et al 1996⁶⁶, Stavrou et al 2002⁶⁷)

ADVERSE EFFECTS OF ANTI-TUBERCULOSIS TREATMENT:

Psychiatric adverse effects in the treatment of tuberculosis has been reported widely and is associated with poorer outcome and increased mortality rates (Baghaei et al 2011)⁶⁸

Isoniazid has been reported in terms of psychiatric adverse effects with a prevalence rate of 1. 9/100⁶⁹ patients and the first mention of this in the literature is in 1956 (Cohn et al 1957)⁷⁰ Prodrome of psychosis featured by anxiety, emotional lability and facial twitching has been reported with Isoniazid (Wasik et al 1970)⁷¹

MECHANISM /THEORIES

ISONIAZID:

Psychosis due to Isoniazid is due to the effect of depletion of pyridoxine (vitaminB6), which is the mechanism whereby neuropathy occurs. Although pyridoxine supplementation is recommended in patients taking isoniazid who are at risk of neuropathy due to underlying medical conditions, such as diabetes, uraemia, alcoholism and HIV infection, it is not effective in the treatment of psychosis secondary to isoniazid (Chan et al 1999)⁷²

Another mechanism by which Isoniazid induces psychotic symptoms is its ability to act as a monoamine-oxidase inhibitor (MAOI), with alteration of the metabolism of catecholamines, which could theoretically induce a manic psychosis in patients with a predisposition to mood-instability (Alao AO et al 1998)⁷³

Isoniazid was the first of the MAOIs to be considered for the treatment of mental disorders in the 1950s, when it was found to be associated with improvements in the mental states of patients with psychiatric disorders, both in those with and those without psychosis, with some patients noted to be “inappropriately happy” (Rosenfeld et al 1955)⁷⁴

Isoniazid may interact with antidepressant medications, and this is based on its action as a weak MAOI (Robinson et al 1968)⁷⁵ Sullivan et al⁷⁶ described 41 patients presenting to a New York city emergency department with isoniazid toxicity, 27 of whom reported attempting suicide by this means. One

study compared suicides in patients with tuberculosis with those with other cardio-respiratory illnesses, found excess in number of suicides in the tuberculosis group, which is attributed to anti-tuberculous agents (Farberow et al 1966)⁷⁷

CYCLOSERINE

It is a cell wall inhibitor acting as a D-Alanine substrate penetrating the blood-brain barrier associated with 20-33% increase of psychiatric illness. (Helmy. B 1970)⁷⁸ Mechanism of action is, diminished central nervous system (CNS) production of -aminobutyric acid (GABA) caused by inhibition of glutamic decarboxylase (Berning et al 1999)⁸⁵. Emotionally unstable personality, history of alcoholism and female sex are predisposing factors for the development of cycloserine induced psychosis. (Bankier RG 1965)⁷⁹ Cycloserine is contraindicated in patients with seizure disorder and psychiatric illness with agitation (Kass et al 2010)⁸⁰

RIFAMPICIN

Rifampicin is a potent cytochrome P 450 enzyme inducer and results in reduction in the serum levels of drugs like sertraline (Markowitz et al 2000)⁸¹ which produces discontinuation syndrome and also reduce methadone levels in opiate dependent individuals warranting increase in dose of methadone during co-treatment with methadone (Backmund et al 2000)⁸²

LINEZOLID

Linezolid causes serotonin syndrome in patients receiving multiple anti-depressants and the incidence was proved to be 35% (Lawrence et al 2006)⁸⁴. The average time of onset was 9. 5 days from the day of commencement of treatment and the average duration was 2. 7 days (Morales et al 2005)⁸³

OTHER DRUGS

Ethambutol associated with mania and psychosis (Pickles et al⁸⁶ 1996, Hsu et al⁸⁷ 1999) Fluoroquinolones have been implicated in rare occurrences of psychosis (Mulhall et al 1995)⁸⁸ and depression (Feinberg et al 1995)⁸⁹

SUICIDE IN TUBERCULOSIS PATIENTS

Karl peltzer et al⁹⁰ 2013, states the predictors for suicidal ideation in a tuberculosis patient as being female, being a TB retreatment patient, psychological distress. Risk factors for a suicidal attempt are being a TB re-treatment patient, had decided to stop TB treatment before, PTSD symptoms, harmful alcohol use, having one or two other chronic illnesses and having ever been diagnosed with an Sexually transmitted infection⁹³.

Scales used in Karl Peltzer et al study are PC-PTSD and K-10. Components of PC-PTSD are re-experiencing, avoidance, hyperarousal and numbing. The Kessler Psychological Distress Scale K10 shows symptom

pertaining to non-specific depression, anxiety and substance abuse, but does not measure suicidality or psychoses

Suicidal ideation was found to be 9% and attempt was found to be 3.1% (Karl peltzer et al)⁹⁰ Factors like neuropsychiatric morbidity, alcohol and drug abuse, behavioral disorders found to increase the risk for suicide (Starace 1995)⁹¹

Suicide was very high in cases of Multiple drug resistant tuberculosis who were on Category 2 drugs and had co-morbid illnesses like deafness, lung abscess, Arthralgia, HIV/AIDS, extra-pulmonary spread, moderate/severe TB (Lasebikan)⁹² and medical comorbidity is found to be an independent risk factor for suicide (Conwell et al)⁹⁷

Atilola et al⁹³ found that certain groups like Yoruba were highly susceptible for suicide as death was preferred to shame, dishonor and indignity associated with chronic respiratory illness like tuberculosis and its due to social cognition.

Alcohol precipitates suicide by means of its serotonin lowering mechanism (Kamali et al 2001)⁹⁴ disinhibitory effects, as a result of intoxication or addiction (Meninger 1938)⁹⁵ and due to the pain (Fishbain 1999)⁹⁶

Depression is found to be a strongest predictor for suicide (Guruje et al 2007)⁹⁸ Causes of depression in tuberculosis patients are release of pro inflammatory mediators like interleukin-6 (Kiecolt et al)⁹⁹ which can be the

result of a chronic condition and biologically results in a depressive illness, hypoxia associated with tuberculosis also results in anxiety and depression (Fenty et al)¹⁰⁰, other causes are loss of weight, fatiguability and psychological losses (Mikkelsen et al 2004)¹⁰¹

Mann et al study¹⁰² in Nigeria recommends that to understand the nature of suicide and its high, certain programs like “Gatekeeper training program” to be included in tuberculosis control program which is currently not available in many countries.

Ige OM et al¹⁰³ states the prevalence of depression as 13. 4% and psychosis as 2. 7% in care givers of tuberculosis and necessitate the need for tuberculosis control program for care givers.

Presenting complaints of depression varies with the general population as somatic complaint is the common presenting complaint along with fatiguability, anhedonia, insomnia (Nutt et al¹⁰⁴ 2001, Cavanaugh et al¹⁰⁵ 1998, Patel¹⁰⁶ 2001)

DEPRESSION

Depression is the most common psychiatric diagnosis in tuberculosis which is associated with a high chance of morbidity and mortality (Prince M et al⁵⁴ 2007, Duarte et al¹⁰⁷ 2009) as well as poor drug adherence as depressive patients fail to seek medical attention for their physical complaints also due to the lethargy and fatiguability associated with depression.

Balkissou et al¹⁰⁹ gives the prevalence of depression in tuberculosis patients as 30.9% Female gender, BMI<18.5kg/metre², retreatment for PTB due to previous default or relapse, a family history of psychiatric illness, stigma associated with the illness, discontinuing anti-tuberculosis treatment and co-morbid illness like HIV has high chances of depression (Jules Kehbila et al¹⁰⁹), Cardiovascular illness, chronic obstructive pulmonary disease, Diabetes mellitus and previous history of depressive episodes are the other risk factors associated with depression. Loss of libido, physiological role of adrenal gland in mediating effects on stressful life events impedes the course of tuberculosis and Adrenal- cortical activity plays a vital role in the treatment resistance to tuberculosis (Supriya adipudi et al)¹¹³

Features associated with depression are worthlessness, hospitalization, social stigmatization and loss of income which lead to self-depreciation, conscious and unconscious fear of chronicity and death (Tandon et al¹¹⁰, Morris et al¹¹¹).

Cough is found to be an independent risk factor associated with depression as the patient and care givers perceive the illness as a worsening one and also the treatment ineffective which increases the patients's burden. Cough produce impairment in work place, school, affects sleep and social life. Patients with chronic cough must be screened for depression and they benefit from depression treatment (French CL et al 1998)¹¹²

Stressful situation precipitated by the illness results in functional impairment, social and respiratory isolation, fear of spreading the illness to others, lowering of self esteem, incapacitation due to the chronicity of the illness (Kelly et al¹¹⁴, Argiro et al¹⁷) Depressive individuals are prone for substance abuse and tend to have unprotected sexual intercourse which results in sexually transmitted illness like HIV-AIDS (Prince M et al)⁵⁴

Depression among tuberculosis patients is very common than the general population after a mean duration of 6.5 years and has got an adverse effect over the quality of patient-physician relationship and so they tend to make frequent visits to physician for vague somatic complaints but delay the visits in times of important medical complications (Yen et al¹¹⁵, Katon et al¹¹⁶, Prince M et al⁵⁴)

Stigma is a significant contributor and study by Ayla et al¹¹⁷ shows that nearly 50% of the patients who got discharged couldn't re-unite with their respective families due to the hostile nature and stigma of the family members.

Study by Muhammad Anwar et al¹¹⁸ compares the prevalence of depression among tuberculosis with that of other chronic medical illnesses and states that among 80% of the depressive patients, 45.8% were suffering from moderate depression and 37.8% were severely depressed when compared with 56.1% of depression in patients receiving hemodialysis, 88.2% of depression

in patients with chronic liver disease, 51. 9% of the patients with dermatological illness who were diagnosed with depression.

Olusoji et al¹¹⁹ states that nearly 22% of the patients were severely depressed and they never sought for any medical attention for their depressive symptoms and 13. 4% of the primary care givers were severely depressed secondary to the chronicity of the illness, sacrifices made by them and as they spend entire day in care giving which poses a serious public health threat and extended family system was found to be a protection factor against depression.

Study by Kunal Kumar et al¹²⁰ says that before the diagnosing tuberculosis, patients present with symptoms of apprehension about the future, irritability, insomnia, restlessness, reduced appetite and interaction with others due to the fear of the illness and uncertainty about the diagnosis. After confirmation of diagnosis, patients tend to have a sense of relief immediately but slowly become depressed, irritable, anxious, and exhibit episodes of aggression towards family members due to excessive worry about the nature of illness and its complications.

Adolescents were found to be much bothered about their body image and functioning, tend to abuse alcohol and substance more, had poor drug compliance, reduced appetite, more non-co-operation and hostility towards the staff and the physician and suicide was low when compared to that of older adults¹²⁰

MANAGEMENT

Reduction of stigma, counseling by health care providers regarding drug adherence, maintenance of self care and diet, avoidance of opportunistic infections, found to be a vital move in reducing the psychiatric disturbance among tuberculosis patients (Amare deribew et al)⁵⁵

Quality of life was a useful tool in assessing the impact of common mental disorders in tuberculosis patients and co-morbid HIV infection was associated with reduced scores in the quality of life measures⁵⁵ Stangl et al¹²¹ study (2007) in Uganda found that in tuberculosis patients with co-morbid HIV, 12 months course of Anti-retroviral treatment produced a significant improvement in mental status and quality of life of the patient.

Regarding the pharmacological management, antidepressant like Citalopram were found to be metabolized by CYP2C19 and CYP3A4 both are inhibited by Isoniazid, which results in increased serum concentrations of citalopram, hence not preferred in depression patients on isoniazid. (Adam Trenton et al)¹²²

Doherty et al⁴⁵ says that Isoniazid and Linezolid itself has got Mono Amine Oxidase Inhibitor property and acts as an antidepressant though MAOI are currently the third choice of drug for depression after SSRIs and Tricyclic antidepressants.

WHO guidelines¹³¹ suggest that patients on anti-tuberculous drugs presenting with depression must be assessed for co-existing substance abuse,

individual or group counselling must be initiated in those patients and regarding pharmacological management, drugs like amitryptaline or fluoxetine can be prescribed and SSRIs and tricyclic antidepressants can be prescribed to the same individual but should not be given to those patients receiving linezolid. Lowering the dose of cycloserine and ethionamide to 500mg/day or stopping the suspected drug without compromising the regimen can be initiated, depressive symptoms fluctuate during therapy and might revert back to normal once the illness is treated successfully, suicidal ideations must be assessed once the diagnosis of depression is made, cycloserine should not be started in case of previous history of depression.

In case of suicidal ideation, patient must be hospitalized and put under 24 hour surveillance, cycloserine must be stopped, anti depressant treatment must be initiated, lower the dose of ethionamide to 500 mg/day, hospitalization must be continued till the risk of suicide passes off and if no improvement, ethionamide should also be stopped¹³¹

PSYCHOSIS

ISONIAZID

Psychosis in a tuberculosis patient is mostly secondary to drugs like Isoniazid and Ethambutol where Isoniazid causes depletion of Vitamin B₆ (Pyridoxine) which interferes with tryptophan metabolism and reduces pyridoxal 5 phosphate which again reduces Gamma Amino Butyric Acid and other neuro transmitters resulting in neurological side effects. (Girling D. J 1984)¹²³ Other precipitating factors for the occurrence of a psychotic illness are advancing age, Diabetes Mellitus, liver insufficiency, alcoholism (Prasad et al)¹²⁴

Clinical features of Isoniazid induced psychosis were excessive adamant speech, grandiosity, aimless wandering, irritability, aggression, emotional instability, delusions, sleep disturbance which started after initiation of treatment and most of the patients lacked prior episodes of psychiatric illnesses and symptoms subsided spontaneously without any treatment as soon as the drug was discontinued. (Jackson¹²⁵, Agarwala et al¹²⁶, Bedi¹²⁷)

Siddarth Arya et al¹³⁰ reported psychosis within 3 days of starting Isoniazid along with clinical features like loosening of association, echolalia and previous neurological insult as a risk factor.

ETHAMBUTOL

Another common drug used in the treatment of tuberculosis causing neurological side effects like retrobulbar neuritis and occurrence of psychosis is very rare¹²⁴Hsu et al⁸⁷ describes the clinical features of ethambutol induced psychosis as dizziness, disorientation, auditory and visual hallucinations within 7 days of the intake of the drug.

TUBERCULOUS MENINGITIS

Irrelevant talk, irritability, disorganized behavior, reduced oral intake and constipation, defective social interaction, dull and withdrawn behavior, sleep disturbances, on and off headache were the presenting features in a case of tuberculous meningitis which presented as acute psychosis (Atmesh Kumar)¹²⁸ Rahim¹²⁹ describes stupor, social isolation, mutism and akinesia in a patient with tuberculous meningitis.

MANAGEMENT

Prasad et al¹²⁴ describes that there are no specific treatments for Isoniazid induced psychosis as symptoms reduce after removing the offending drug and Pyridoxine which is used in the treatment of Isoniazid induced neurological manifestations failed to show effectiveness in the case of a psychosis.

Rahim¹²⁹ states that psychosis secondary to tuberculous meningitis improved with anti-tuberculous drugs and steroids

WHO Guidelines¹³¹ suggest that in patients with psychosis, suspected drugs like cycloserine and isoniazid should be stopped atleast for 2-4 weeks while psychotic symptoms are under control, patients at risk to themselves and to others must be hospitalized, in cases of moderate- severe psychotic features first generation drugs like Haloperidol must be started, cycloserine dose must be reduced to 500mg/day and pyridoxine dose must be increased to 200mg/day, if the patient is completely off cycloserine, anti psychotics can be stopped and if cycloserine is continued or restarted, low dose anti psychotics to be continued.

Previous history of psychiatric illness, though not a contraindication to cycloserine therapy increases the future risk of psychotic episode and reduced renal parameters increases the serum concentration of cycloserine and results in psychosis.

ROLE OF ALCOHOL

Karthikeyan Duraisamy et al¹⁸ found that among default patients, alcohol consumption was found to have a hazard ratio of 4.3 but it was not found to be an independent risk factor for default and death during treatment, patients with alcohol consumption were found to miss more than 7 intensive phase doses and on average about 18 when compared with patients who do not drink alcohol.

Study by Beena Thomas et al³⁷ found that many patients stated their alcohol consumption was the main reason behind their diagnosis of tuberculosis as loss of appetite set up an immunologically suppressed condition making them vulnerable to acquire tuberculosis and few respondents also said that consuming alcohol during tuberculosis treatment adversely affect the outcome, few said that they couldnot quit alcohol during the treatment course and if they had a drink, they would fear about the drug and alcohol interactions and would avoid visiting TB clinic due to the fear of being reprimanded by the physicians.

Alcohol consumption more than 40gms/day was associated with increased chances of smear positive cavitory pattern, longer duration for smear conversion and increased chances of drug toxicities (Brown et al¹³², Lonnroth K, Williams BG et al¹³³, Francisco et al¹³⁴, Fiske et al¹³⁵) Drug resistant strains of Mycobacterium is also common among alcoholics (Romanus et al)¹⁴²

Samai Laprawat et al¹³⁶ gives the following three different patterns of drinking among patients on tuberculosis treatment

- 1) Few patients tend to stop alcohol during the beginning of the treatment but after 3-4 months succumb back to drinking once their general condition improves.
- 2) One set of patients completely quit their alcohol consumption after the therapy which significantly improved their relationship with their family members
- 3) Third group which continued the alcohol consumption during the course of treatment

Certain factors for the decline in alcohol consumption highlighted by Samai Laprawat et al¹³⁶ are intervention strategies attempted by the health care providers, adverse effects of taking alcohol along with anti tuberculosis drugs and change in the natural changes in the pattern of drinking during the course of the treatment

Daxini Arvind et al¹³⁷ study on 150 treatment defaulters and 150 treatment completed control groups showed that odds ratio for alcoholism between cases and controls were 4.75 which proves that patients consuming alcohol during the course of treatment have 375% more chances of defaulting when compared with that of patients who do not drink.

People using alcohol forget to take anti-tuberculosis drugs leading to default and continued alcoholism compromise liver function tests which increase the hepatotoxic side effects of the drugs (Nirmalya Roy et al)¹³⁹

Daily consumption of alcohol at the start of the treatment was associated with high chances of lost to follow up and patients with alcoholism tend to move out of their residence often, give false addresses, reside in slum areas, difficult to locate, abandon treatment more often (Ibrahim et al 2012)¹⁴⁰

Venkateswarlu et al¹⁴¹ says that nearly 25% of the patients who defaulted from treatment were consuming alcohol and more than half of the defaulters and treatment failures spent money on alcohol.

Defaulters tend to remain infectious and poses a threat to their families as well the community because the mycobacterium strain become resistant to first line anti-tuberculous drugs (Farah et al 2005)¹⁴³

Under the influence of alcohol, patients exhibit altered behavior and have more side effects leading to default and relapse (Sonam lepcha et al)¹⁴⁴ Alcoholism alters the metabolism of anti tuberculosis drug like Isoniazid, lowers the serum concentration of the drug, shortens the half life, reduced absorption of the drug resulting in treatment failure and poor outcome (Koriakin et al)¹⁴⁵

Hector¹⁴⁷ in his post mortem studies found that alcoholism was a common antecedent factor in individuals without a genetic predisposition

towards tubercle bacilli and also that broncho pneumonic consolidation was the most common type of tuberculosis in patients with alcoholism

ALCOHOL IN GRAMS AND ITS EFFECT ON TUBERCULOSIS:

Alcohol consumption was responsible for 10% incident cases and deaths reported (Jurgem Rehm, Samokhvalov et al)¹⁴⁶ Sameer Imtiaz¹⁴⁸ meta-analyses study gives the risk of tuberculosis associated with alcoholism as 35% when compared with that of the population which doesnot drink. Past alcohol use was not significantly associated with tuberculosis when compared with that of absenteeism. In this study, increase in risk based on grams of ethanol was given as 1. 57 at 25 grams of ethanol, 2. 46 at 50 grams, 3. 85 at 75grams, 6. 03 at 100grams. Alcohol consumption more than 60grams/day was associated with 68% increased risk of tuberculosis when compared with that of no alcohol. Tuberculosis attributable to alcohol consumption was found to increase by 50% in many countries.

Higher consumption results in higher attributable tuberculosis disease burden (Rehm J, Anderson P et al 2013)¹⁴⁹Men who consume more than 38 grams of ethanol were not found to be at increased risk for tuberculosis but the risk started to increase by four fold thereafter but women who drink were not found to be at increased risk for tuberculosis. (Francisco et al)¹³⁴

Molecular epidemiological studies implicate the spread of tuberculosis is facilitated by alcohol consumption in social situations like bars, prison, social institutions. (Diel et al¹⁵⁰, Zolnir et al¹⁵¹, Cassen et al¹⁵²)

After controlling the factors like age, sex and smoking on alcoholism, Kolappan et al¹⁵⁶ found that patients who consume alcohol were found to be associated with 1.5 times higher risk than persons who do not consume alcohol.

Relative risk of 2 for heavy alcohol consuming patients was reported by Buskin et al¹⁵⁷ Coetzee et al¹⁵⁸ found the relationship between problem alcoholism in household, overcrowding and its relation with the spread of tuberculosis. Coetzee gives the definition of a household with alcohol problem as “a household in which atleast one member reports alcohol as a problem” There was a significant association between alcohol problems in the household and tuberculosis risk which was independent of the employment status and the result was confirmed by many other tuberculosis research workers.

Maria de fathima et al¹⁵⁹ study says that people who drink everyday or who find difficulty in cutting down their daily alcohol were at increased risk for treatment failure in tuberculosis as well as have combined negative outcome which is nothing but the increased chances of developing tuberculosis and poorer response to treatment.

Baski et al¹⁶⁰ study define heavy drinkers as those who drink average of 3 or more drinks daily or more than average of 5 every time he drinks”, heavy drinkers were twice the risk of developing tuberculosis when compared with non-heavy drinkers as they tend to lack homes, never attended

rehabilitation treatments, had poor nutritional status and ciliary function to get rid of tubercle bacilli

Vidal et al¹⁶¹ found that in the prospective study of 1235 patients, hepatotoxicity was found to be present in 36% of the patients with risk factors like alcoholism and chronic alcohol induced liver disease when compared with the 13% of the patients without any of these risk factors.

Carola et al¹⁶² found that in patients who developed serious liver damage with elevated serum transaminases >150 units/litre on treatment with Isoniazid and Rifampicin were mostly men with chronic history of alcoholism.

Alcohol as a risk factor is confirmed by Crampin et al¹⁶¹ but this finding was found only among ex-drinkers who gave up alcohol after the diagnosis of tuberculosis. Alcohol consumption during the course of treatment make them nutrition deficient resulting in nausea and vomiting, also as the general condition improves with tuberculosis medications, patients resume back to their previous drinking pattern which also results in non-adherence. (Aurora Heemanshu¹⁸¹)

Respondents in Donald Skinner et al¹⁶⁶ study in South Africa say that quitting alcohol during the course of treatment segregate them from their peer groups and social circles and once they get better, they wish to resume back to their social groups.

MANAGEMENT OF TUBERCULOSIS WITH ALCOHOLISM

Beena Thomas et al³⁷ postulate the following framework adopted from Ecological system model by Bronfenbrenner (1979) which includes the following:

“Micro system-which includes the closest relatives and peer groups having bi-directional influence which is both away and towards the alcohol habit of the patient

Meso system-connects micro and health environment

Macro system-being isolated and labeled in the society, stigma attached to excessive and hazardous drinking.

Chrono system-which determines the duration of time on having an influence over the perception of his own drinking pattern exhibiting a positive influence on drug adherence”

Respondents of Beena Thomas et al³⁷ study also expressed the need for awareness about alcohol with pamphlets, audio visual tapes and also that intervention programs have to be integrated with TB programs, they also preferred individual counseling to that of a group counseling and highlighted the need to involve their family members in those programs which increased their drug adherence. Motivated patients pointed their willingness for de-addiction treatment, family members opined that such intervention programs are likely to improve quality of life of the patient as well as other members.

John R Edsall¹³⁸ et al opines that daily regimen of Isoniazid and Rifampicin for a duration of 6 months will be effective in alcoholic patients who tend to have poor adherence, in view of high failure rates in this combination, additional 6 months course of less toxic combination of drugs like isoniazid and ethambutol to be started which accounts for a total duration of 12-24 months of treatment.

For co-morbid Alcohol Use Disorders in tuberculosis patients, Jurgen Rehm et al¹⁴⁶ suggest that strict taxes must be made on the sale of alcoholic beverages and availability must be reduced through coherent liquor outlet policy.

Lonroth, Migliori et al¹⁵³ put forth that elimination of alcoholism in low incidence settings is essential for reducing the incidence of tuberculosis because when tuberculosis incidence reduces, it becomes more and more confined among high risk group like heavy alcohol consumers and those with alcohol related problems and health care workers must be trained in addressing this issue.

WHO End TB strategy 2015 states that, “reducing alcohol and alcohol related disorders is essential to cut down the social determinants of health”. This strategy imply the need for targeting the social determinants which cut down the transmission chains which in turn reduces tuberculosis disease burden. (Lonroth Jeramillo et al¹⁵⁵, Lonroth Castro et al¹⁵⁶) WHO End Tb strategy¹⁶⁴ 2006 recommends the health care providers involved in tuberculosis

treatment to include associations involved in the treatment of alcoholism, opioid abuse, psychological clinics and also religious bodies to improve the drug adherence of the patient.

Naltrexone and behavioral counseling integrated into the tuberculosis treatment improved adherence in one randomized control trial by Shin et al¹⁶⁵ McDonald et al¹⁶⁷ study found that Directly Observed Treatment Shortcourse therapy on Out Patient basis was found to be effective in chronic alcohol dependent individuals in whom ambulatory treatment which was not given under any supervision got failed.

Imtiaz et al study¹⁶⁸ proposes two different approaches for treatment of substance use disorders and tuberculosis. In first approach screening, diagnosis of pattern of alcohol use disorder and plan for effective pharmacology must be implied by health care professionals involved in tuberculosis treatment. In second one, screening of high risk individuals like alcohol users especially vulnerable groups like homeless individuals, people released from prison must be screened for tuberculosis.

ROLE OF PERSONALITY FACTORS

Study conducted in 214 patients by Sudhir et al²⁰ concluded that “53. 2% were neurotic, 26. 2% introverts, 18. 2% were extroverts and 2. 2% had other personality traits” Among defaulters, majority had neurotic personality traits, very few introverts were present and none were extroverts (Vernier et al)¹⁶⁹ Most of the defaulters were found to be less involved in the

environment. Neurotic personality default more and retrieve less when compared with other personality traits. Behavioral modification through effective psychotherapy, repeated counseling increases adherence and improves treatment completion rate when compared with single session (Charles et al)¹⁷⁰

Study by Vinogardov et al¹⁷¹ states that negative attitude towards treatment, impairment in social adaptation, neglect of the generally accepted behavior, schizoid personality traits. Individual response to disease detection were determined by a number of symptom complexes like hypochondriasis (13. 6%) and being paranoid (9. 1%). These traits adversely affected the treatment outcome and a long term management on conservative grounds again worsened the hysterical and schizoid personality traits.

Shirley Brinkerhoff in his book on Personality disorders¹⁷² states that Anti tuberculosis drug Iproniazid which found to improve depression due to its monoamine oxidase enzyme inhibiting action was also found to be effective in avoidant personality disorders as well as in social phobia but requires cautious usage due to its dietary and drug interactions and is not widely preferred now.

Case control study by Janmeja et al¹⁷³ showed that the group with pre treatment psychological assessment and psychotherapy showed better drug adherence and cure rates when compared with control group without psychological intervention and suggests the role of psychotherapy in reducing the rates of relapse, default.

Bansal et al study¹⁷⁴ (2010) conducted in 214 out-patients registered in DOTS centre Kanpur assessed personality factors among tuberculosis patients using 16-Personality Questionnaire states that 54. 1% were anxious personality, 26% were introverts, 15. 8% extroverts and 4. 1% had other personality traits.

Locus of control categorized as internal, powerful others, luck or chance as a predictor of personality factors by Obadiora, A. H¹⁷⁵ states that powerful others is a strong predictor of drug adherence. Among these three, powerful others involving the role of family members and health care workers who provided the directed observed treatment was considered as the psychological predictor of personality based on which treatment packages directed towards improving adherence can be planned.

Immerman et al¹⁷⁶ showed that among 232 patients, 64% of the patients were found to have neurotic traits and anti-tuberculous treatment failed to control the symptoms in nearly 51% of the patients necessitating the inclusion of psychotherapy in the treatment.

PREVELANCE AS PER PREVIOUS STUDIES

Prospective study by Alok Bharadwaj et al¹⁷⁷ defined non-compliance as “The extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice” This study conducted in 44 tuberculosis patients in KLES hospital and research centre found that nearly 13 members were alcoholic (33%) and 26 of the patients were non alcoholic (66%)

Kelly Dooley et al study¹⁷⁸ conducted in 291 patients who have come for re-treatment from a period of one year from June 2008-2009 states that only 2 members were found to have alcoholism (3%) This study states this finding as a limitation as alcoholism is meager in Morocco and so the role of alcoholism in drug adherence couldn't be concluded with this study and the results of this study couldnot be generalised to the population.

In the study conducted by Ana Paula et al¹⁷⁹ to estimate the Health Related Quality of Life, Anxiety and Depression in hospitalized patients with tuberculosis, 119 patients who met the inclusion criteria were enrolled among them, 86 participated in the study, Anxiety and depression were assessed with the help of Hospital Anxiety And Depression rating scale. Results were that more than one-third of the patients had a diagnosis of anxiety (38. 4%) and depression (34. 4%)

Case control study conducted in Nairobi by Muture et al¹⁸⁰ between January 2006 and March 2008 involving 120 cases and 154 controls shows that default rates were higher during the initial 2 months of intensive phase of treatment and also that many factors were individually associated with high default rates. Alcohol consumption leading to forgetting of drug intake was found in 9 patients amounting to 7. 5% and psychiatric conditions were found in 3 individuals, which amounts to 2. 5%

Alcohol abuse, defined as “recurring use of alcoholic drinks despite the negative consequences” was found to serve as a predictive factor for default

with a odds ratio of 4. 97. This study also states that in Nairobi, cheap local brews are found to be sold in very congested places and are hot spots of spreading tuberculosis to others and higher risk of further defaulting. Alcoholism also results in liver damage and causes drug interactions with anti-tuberculosis drugs leading to greater liver damage.

Since alcohol abuse is found to be an independent predictor for default in this study, need to find targeted interventions which improves adherence in tuberculosis patients with co-morbid alcohol abuse is recommended in this study.

Multi-stratified study conducted by Aurora Heemanshu et al in 204 adult tuberculosis patients enrolled in category-1 treatment in New Delhi found that 44 members (21. 6%) had history of alcoholism. Patients with alcohol consumption had 2. 4 times increased risk of treatment default when compared with patients without alcohol consumption.

Aurora Heemanshu et al¹⁸¹ also states that alcohol consumption during the course of treatment was associated with greater default and combined with poor nutrition status resulted in adverse effects like nausea and vomiting. This also highlights the need for continuous and effective health education, repeated motivation and counseling.

Study conducted by Yadav et al¹⁸² in Agra in 272 tuberculosis patients used Wing's screening Present State Examination (PSE) and diagnostic guidelines as per ICD -10 to screen psychiatric illness found that 29. 4%

suffered from a psychiatric co-morbidity, 19. 4% had depression and 6. 6% had anxiety. 36% of the patients treated in the Out Patient set up had a co-morbid psychiatric disorder.

Mathai et al¹⁸³ conducted a study in 70 tuberculosis In-patients and 70 controls who had non-tuberculous bronchiectasis and this study population was followed for a duration of over 6 months in order to avoid reactions secondary to the effects of anti-tuberculosis drugs and also to rule out CNS causes if any. After the initial clinical evaluation, diagnosis was confirmed in accordance with ICD-9. 28. 87% of psychiatric illness was found, among which 15. 7% constituted depression, 7% had anxiety and 3% had alcohol dependence syndrome.

Bhatia et al¹⁸⁴ conducted a study in 50 Out-Patients attending a Tb hospital in Delhi and used EPQ-R (Eysenck's Personality Questionnaire-Revised) to assess neurotic traits and Dysfunctional Analysis Questionnaire (DAQ) Nearly 78% of the patients scored significantly on neuroticism scales and the scores correlated with the subscales of Dysfunctional Assessment Questionnaire and had greater psychosocial dysfunctioning.

Chandrasekhar et al¹⁸⁵ conducted a study in 100 tuberculosis patients in Bangalore using MINI-International Neuro Psychiatry Interview scale found 46% of the patients had psychiatric illness among which 36% had depression, 24% had anxiety and 16% had co-morbid illness of both anxiety and depression. Depression was found in patients belonging to lower socio-

economic status, staying for longer duration as In-Patients, on non-RNTCP group of drugs. Anxiety was found to be predominant in patients with less education and patients who had tuberculosis associated with complications.

Gelmanowa et al¹⁸⁶ conducted a study in 207 patients enrolled in DOTS programme found that 8.8% of the patients defaulted from the study and substance abuse was found to be an independent predictor for default and alcohol was found to be associated with an odds ratio of 4.38 and 6.25 was the odds for reported alcohol use during treatment. Alcohol abuse was associated with an odds ratio of 15.57 for default.

AIMS AND OBJECTIVES

AIMS

To study the prevalence of psychiatric co-morbidity, alcohol abuse and personality factors in tuberculosis default patients.

PRIMARY OBJECTIVE

To study the prevalence of psychiatric illness, alcohol abuse, personality factors among tuberculosis defaulter patients

To study the role of these factors in Anti tuberculosis drug discontinuation

SECONDARY OBJECTIVE

To study the relationship between psychiatric illness, alcohol abuse, personality factors and tuberculosis default

To study the relationship between personality factors and alcohol abuse

To study the relationship between demographic profile and tuberculosis default

HYPOTHESIS

NULL HYPOTHESIS

There is no significant association between tuberculosis default and psychiatric illness.

There is no significant association between tuberculosis default and alcohol abuse.

There is no significant association between tuberculosis default and personality factors.

There is no significant association between various personality factors and alcohol use.

MATERIALS AND METHODS

SETTING

The study was conducted in Government Thiruvoteeswarar tuberculosis hospital Otteri Chennai, a tertiary care centre for tuberculosis in Tamil Nadu. The necessary prior permission for conduct of the study was obtained from Director Tuberculosis hospital and Institutional Ethics Committee, Madras Medical College, Chennai

STUDY POPULATION

Tuberculosis patients who have been diagnosed as default or lost to follow up admitted as In-patients in Government Thiruvotteswarar tuberculosis hospital Otteri Chennai were selected for the study. Patients who have defaulted treatment for atleast 2 months were enrolled in the study.

SAMPLE SIZE:

A total of 110 sample size of tuberculosis patients who defaulted treatment were included in the study.

SAMPLE SIZE CALCULATION:

For this cross –sectional study, sample size calculation was done in accordance with the Muture et al study¹⁸⁰ which shows a 7. 5% prevalence of alcohol use and 2. 5% psychiatric illness as a reason for default.

Formula used in cross –sectional studies to calculate sample size is

$$\text{Sample size} = Z^2 \times p \times q \div d^2$$

Here Z-1. 96

p-0. 075

q-0. 93

d-0. 05

We arrive at a sample size of 96 in accordance with this study and so a sample size of 110 being enrolled in our study.

PERIOD OF STUDY:

The study was conducted for a duration of 4 months from March 2017- August 2017

SAMPLING METHOD:

Non probability sampling cross-sectional

RESEARCH DESIGN:

CROSS-SECTIONAL STUDY:

110 patients admitted as in-patients in Government Thiruvoteeswarar tuberculosis hospital fulfilling the criteria for lost to follow up or default were chosen up for the study.

INCLUSION CRITERIA:

- 1) Patients diagnosed as Tuberculosis default or lost to follow up admitted as in-patients
- 2) Age 20-60 yrs
- 3) Patients who are able to give written consent and wish to participate in the study

EXCLUSION CRITERIA

- 1) Subjects who have other neurological illness
- 2) Subjects with age less than 20 and more than 60 who have other medical illness
- 3) Subjects with medical illness other than tuberculosis default like tuberculosis relapse or sequelae
- 4) Subjects who do not wish to participate in the study

OPERATIONAL DESIGN

After obtaining the written informed consent from the participants as required by the Institutional ethical committee

INSTRUMENTS USED:

- 1) Socio-economic profile
- 2) SCID
- 3) AUDIT
- 4) 5 factor questionnaire
- 5) HAMD
- 6) YMRS
- 7) PDSS

SEMI STRUCTURED PROFORMA:

It was used to collect subject's socio-demographic details like name, age, sex, education, occupation, marital status, address, unemployment in terms of months, diagnosis of tuberculosis in months, past history of tuberculosis, adherence in months during the past episodes, income according to modified Kuppuswamy scale.

SCALES USED:**ALCOHOL USE DISORDER IDENTIFICATION TEST:**

This Alcohol use disorder identification test (AUDIT)¹⁸⁷ questionnaire helps to identify persons with excessive drinking and recognizes hazardous and harmful patterns of alcohol consumption. This provides a base for treatment

and for planning individualized deaddiction programmes. It has got 10 questions. 1st to 3rd question are on alcohol consumption; 4th to 6th are on alcohol drinking behaviour and dependence; 7th to 10th questions are on the consequences or problems related to drinking.

1st to 8th question – scored as 0, 1, 2, 3, 4 on five –point scale.

9&10th question –scored as 0, 2, 4 on a three –point scale.

Maximum score-40

YOUNG MANIA RATING SCALE:

This Young Mania Rating scale (YMRS)¹⁸⁸ is used to assess the severity of the manic symptoms during the episode and during the recovery phase. It consist of 11 items scored on a likert scale 0 to 8 for four items, 0 to 4 for 7 items. Reliability is good based on inter-rater reliability studies.

HAMILTON’S RATING SCALE:

Max Hamilton first introduced this Hamilton’s rating scale [HAM-D or HDRS]¹⁸⁹ in 1960. It is accepted widely and used to assess the severity of the depression and helps as a follow up guide to assess the treatment response in the recovery phase.

It has high inter-rater reliability and validity. Many version of HDRS are available. In HAM-D 21 item version only 17 items were given scores and others are taken up for clinical information like hypersomnia, increased

appetite and concentration and indecision. It takes about 20 minutes to administer.

Eight items scored from 0 to 4 and other 9 items are scored from 0 to 2.
[0= not present;4=very severe].

NORMAL	MILD	MODERATE	SEVERE	VERY SEVERE
0-7	8-13	14-18	19-22	≥ 23

SCID (STRUCTURED CLINICAL INTERVIEW FOR DSM DISORDERS)

SCID module was used to screen psychiatric illness and patients who fulfill the criteria were assessed with scales and scoring was made.

5 FACTOR MODEL RATING FORM:

Patient self-rated questionnaire where the patient must rate themselves on a 1-5 scale on the personality traits, 30 in number. Scoring from 1-5

1-Extremely low

2-Low

3-Neither high or low

4-High

5-Extremely high

PANIC DISORDER SEVERITY SCALE:

Clinician rated scale to assess the severity of panic disorder. 7 item questionnaire to rate the overall severity of individuals already diagnosed as panic disorder. It assess symptoms over the past one month. It provides information about the frequency of panic attacks, panic focused anticipatory anxiety, avoidance of agoraphobic situations, avoidance of panic related physical sensations, impaired social and occupational functioning (shear et al)¹⁹¹

SCORING:

0-none

4-Extreme

Total score- 0-28

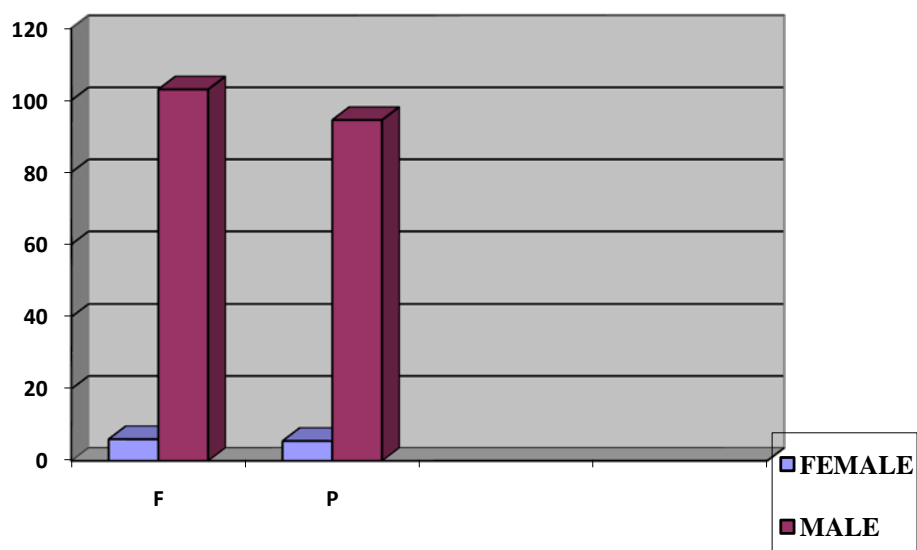
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RESULTS AND OBSERVATIONS

SOCIO-DEMOGRAPHIC PROFILE

SEX

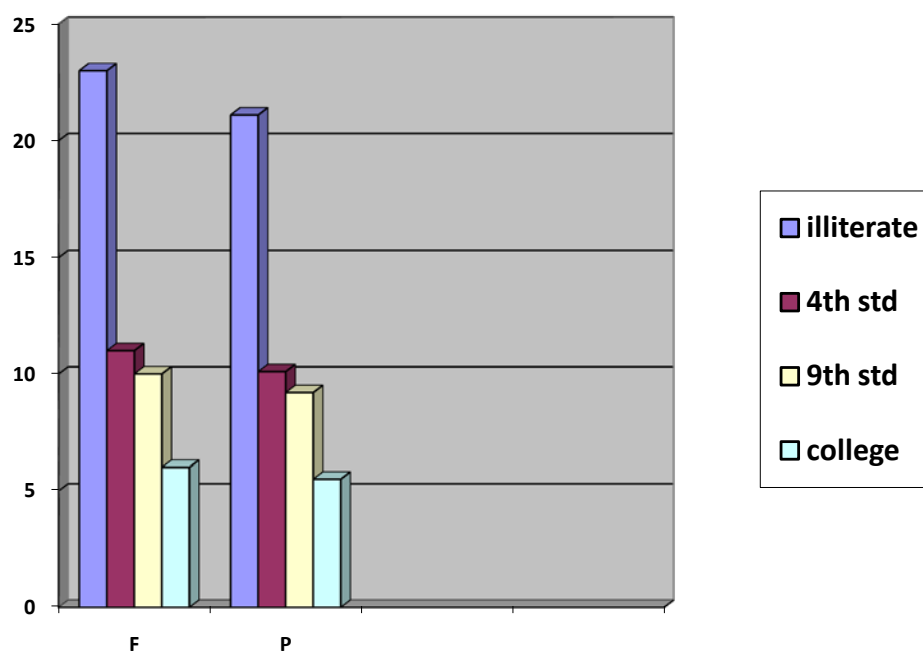
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	F	6	5.5	5.5	5.5
	M	104	94.5	94.5	100.0
	Total	109	100.0	100.0	



F-Frequency and P-Percentage in all the graphs

Males constituted 94.5% and females constituted 5.5% of the total sample collected.

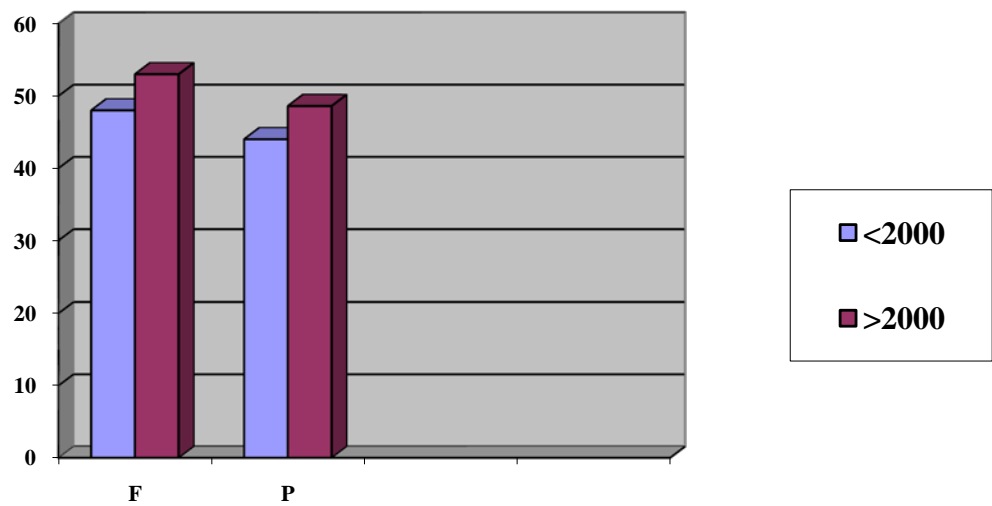
EDUCATION:



In this sample 23 members (21%) were illiterates, 11 members (10%) studied upto 4th class followed by 10 members (9. 2%) studied upto 9th std whereas only 6members (5. 5%) entered college

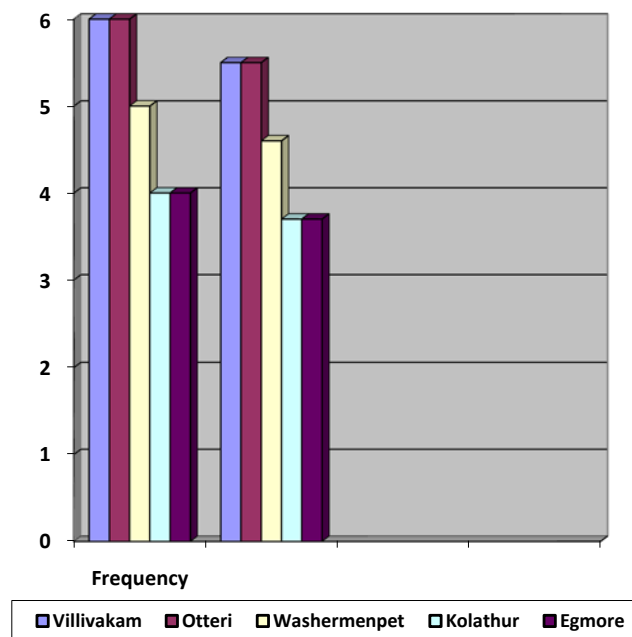
INCOME:

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<2	48	44. 0	44. 0	44. 0
	>2	53	48. 6	48. 6	92. 7
	0	8	7. 3	7. 3	100. 0
	Total	109	100. 0	100. 0	



In this sample, 53% had income above 2000 rupees and 48% found to have income less than 2000 rupees.

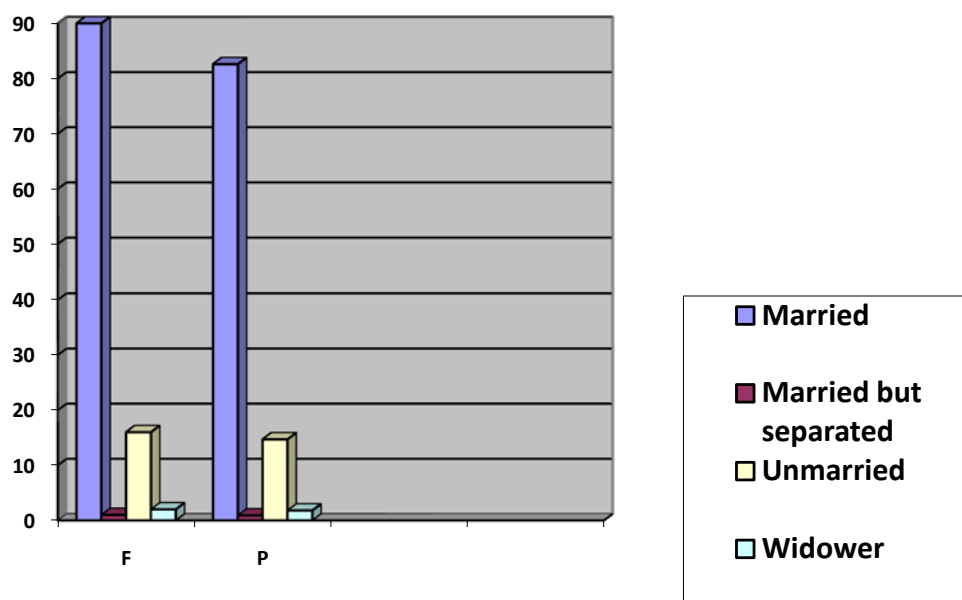
PLACE:



In this sample, 6 members (5. 5%) were from Villivakkam and Otteri, 5 members were from Washermenpet (4. 6%), 4 members (3. 7%) were from Kolathur and Egmore.

MARITAL STATUS:

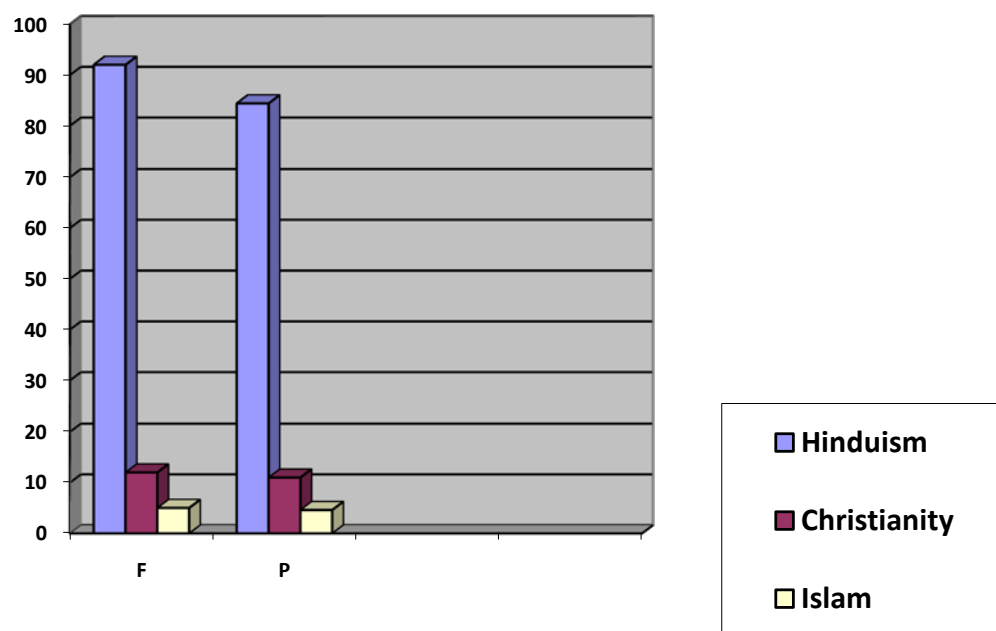
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	M	90	82. 6	82. 6	82. 6
	M, S	1	. 9	. 9	83. 5
	UM	16	14. 7	14. 7	98. 2
	W	2	1. 8	1. 8	100. 0
	Total	109	100. 0	100. 0	



In this sample, 90 members (82. 6%) were married, 16 members were unmarried (14. 7%), 2 were widower (1. 8%), 1 was married and separated (0. 9%)

RELIGION:

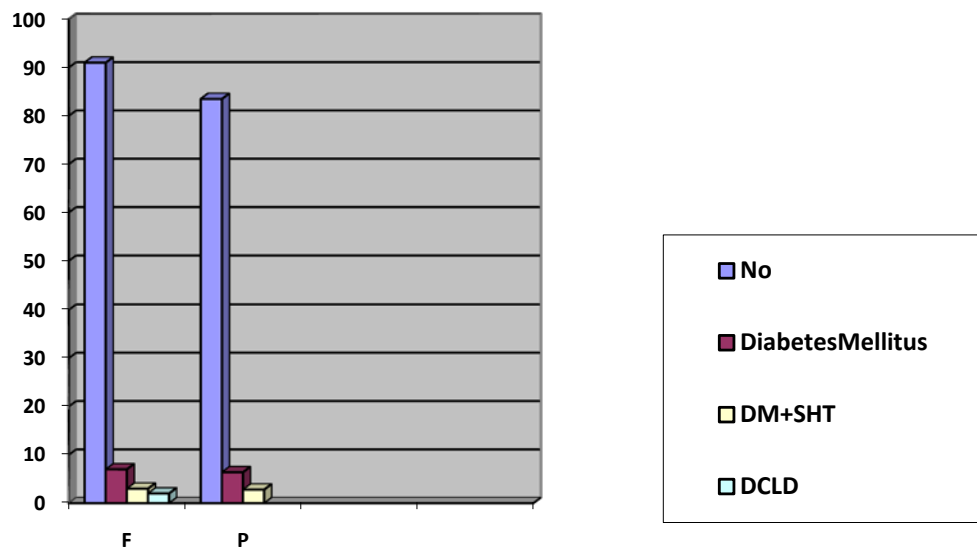
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	C	12	11.0	11.0	11.0
	H	92	84.4	84.4	95.4
	M	5	4.6	4.6	100.0
	Total	109	100.0	100.0	



In this study, 92 members (84.4%) were following Hinduism, 12 members (11%) were following Christianity, and 5 members were following Islam (4.6).

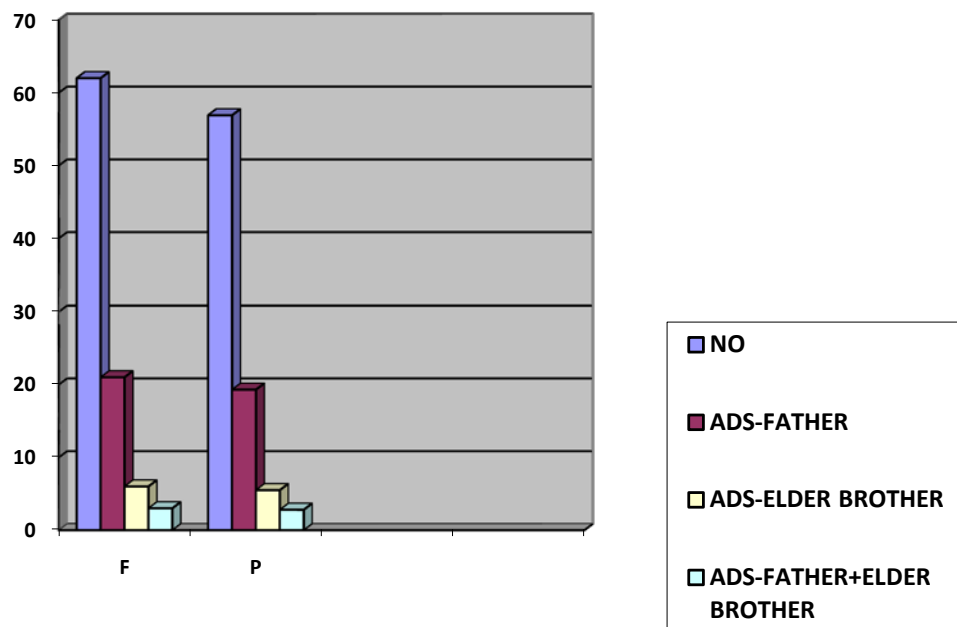
CO-MORBID ILLNESS:

91 members (83.5%) had no comorbid illness, 7 had Diabetes Mellitus (6.4%), Diabetes Mellitus and Systemic Hypertension was found in 3 members (2.8%), Decompensated Liver Disease was found in 2 members (1.8%)



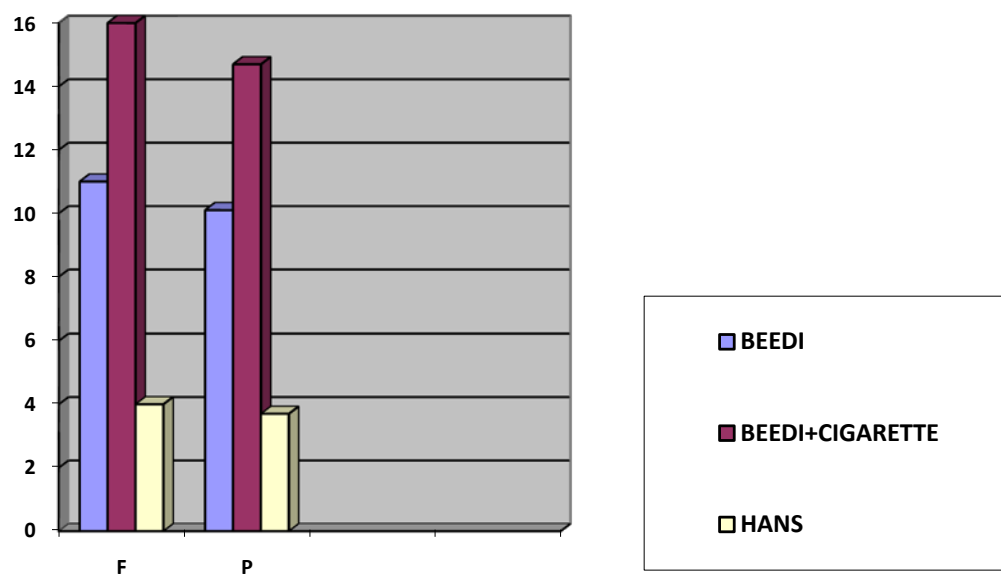
:

FAMILY HISTORY OF PSYCHIATRIC ILLNESS:



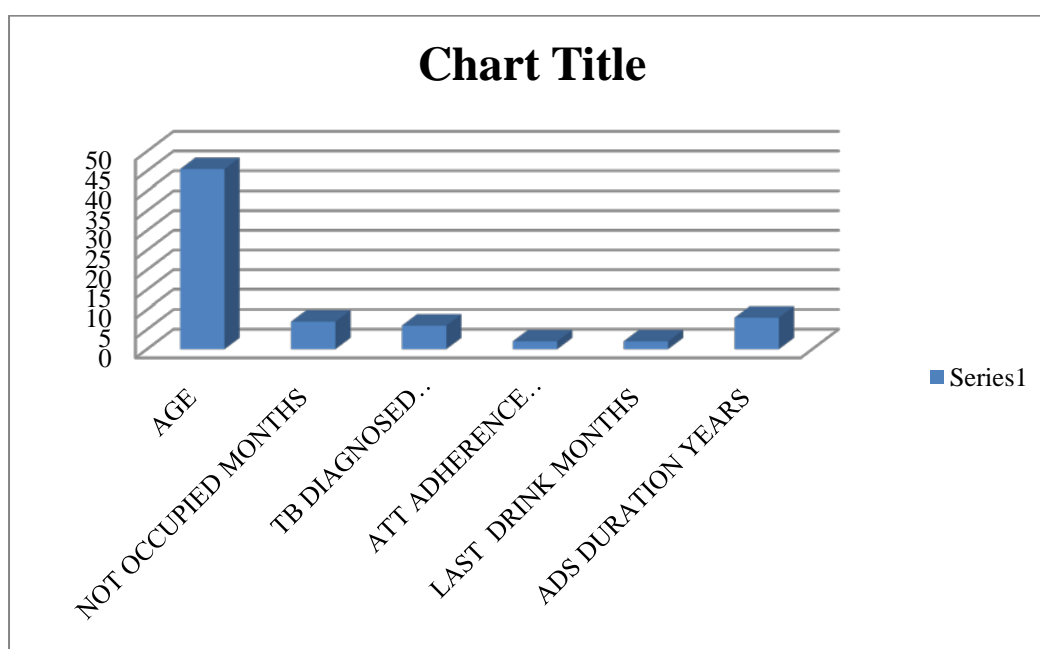
In this sample, 62 members (56. 9%) had no family history of psychiatric illness, 21 members reported alcohol dependence pattern in their father (14. 3%), 3 reported alcohol dependence in their elder brother (2. 8%)6 members reported alcohol dependence in their elder brother and father (5. 5%)

OTHER SUBSTANCE USE:



Apart from alcohol, beedi smoking was reported by 11 (10. 1%), beedi and cigarette smoking reported by 16 (14. 7%), Hans usage by 4 members (3. 7%)

SUMMARY OF DEMOGRAPHIC DATA RESULTS

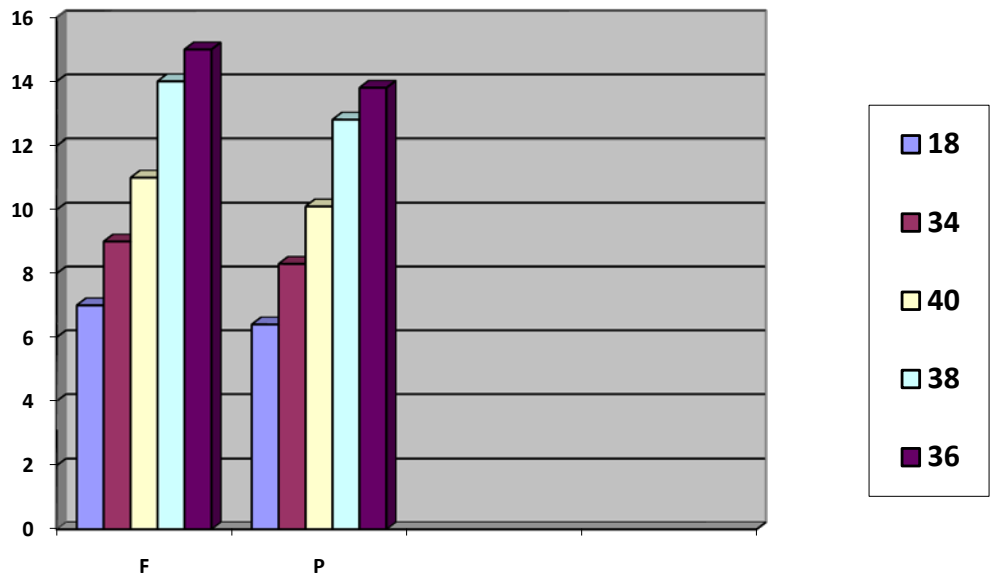


Regarding age, mean age was found to be 45 years (Range 37-53). Median value for number of months not occupied is 7 months (Range 3-12), Months before which tuberculosis was diagnosed had a median value of 6 months (Range 4-6 months), ATT adherence in months has a median value of 2 months (Range 1-3), Last drink in months value was found to have a median value 2 months (Range between 15 days-3 months). Alcohol Dependence in years found to have a median value of 8 years which fell midway between 3-15 years.

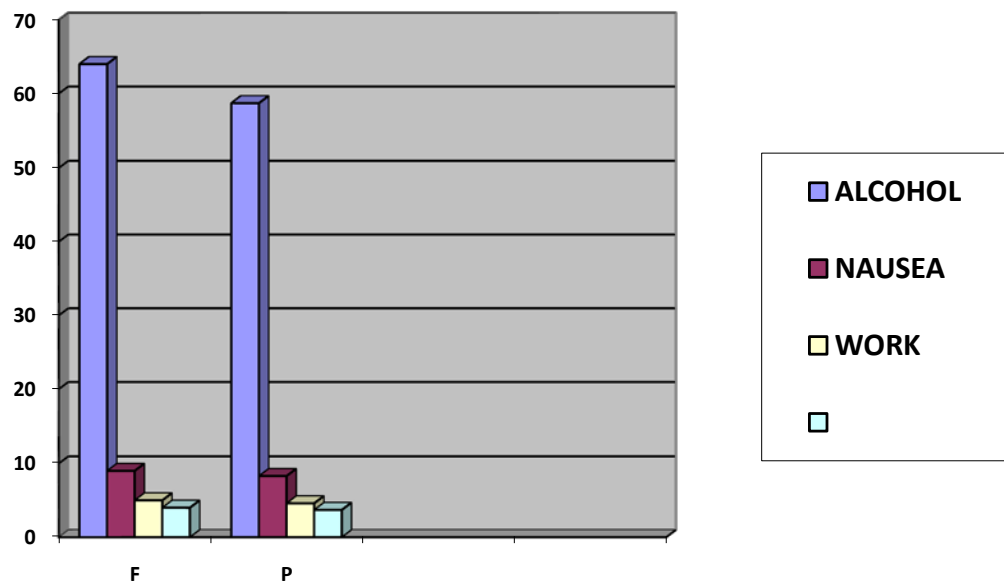
ALCOHOL DEPENDENCE:

	Frequency	Percent
N	30	27.5
Y	79	72.5

79 members (72.5%) reported alcohol dependence syndrome in this sample. AUDIT score Above 8 was found in this sample.



7 members (6. 4%) had score of 18, 9 had score 34 (8. 3%), 11 had a score of 40 (10. 1%), 14 had a score of 38 (12. 8%), 15 had a score of 36 (13. 8%)



In this sample, 64 members (58. 7%) stated alcohol consumption as the reason for quitting anti tuberculosis medicines, Others were nausea by 9 members (8. 3%), 5 stated the reason as work (4. 6%), 4 (3. 7%) said that they felt good after the intensive phase and so only they quit the drug.

COMPARISON BETWEEN ALCOHOL DEPENDENCE AND OTHER PARAMETERS:

ALCOHOL AND INCOME

			INCOME/MONTH		
			<2	>2	0
ADS	N	Count % within ADS	10 33. 3%	15 50. 0%	5 16. 7%
	Y	Count % within ADS	38 48. 1%	38 48. 1%	3 3. 8%
Total		Count % within ADS	48 44. 0%	53 48. 6%	8 7. 3%

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	5. 999 ^a	2	. 050

48 members with alcohol dependence had income less than 2000 (44%) and with a significant p value of 0. 05

ALCOHOL AND PSYCHIATRIC ILLNESS:

Among 4 members who had psychiatric illness, 2 had alcohol dependence syndrome. p value is not significant in this group.

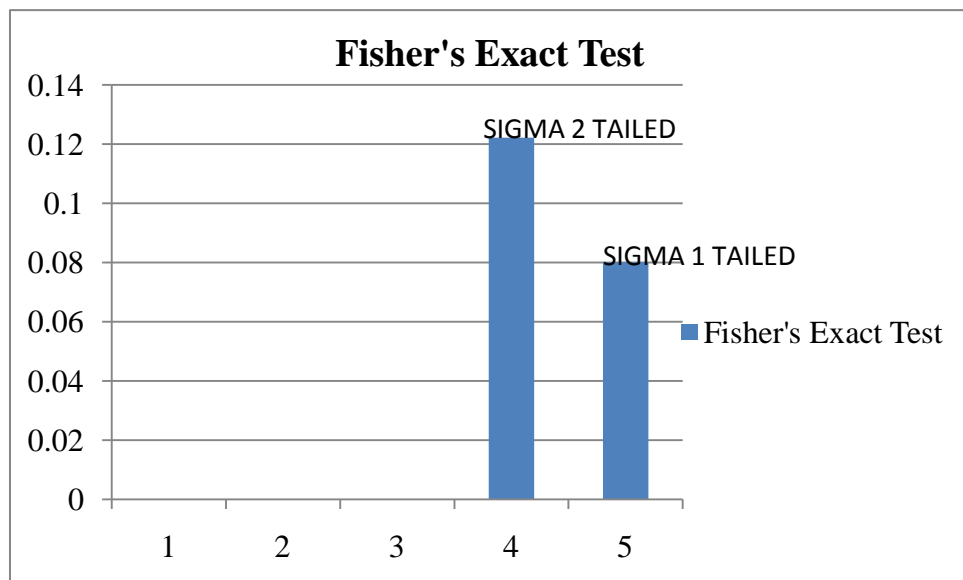
			Psychiatric illness	
			Yes	No
ADS	N	Count % within ADS	2 6.7%	28 93.3%
	Y	Count % within ADS	2 2.5%	77 97.5%
Total		Count % within ADS	4 3.7%	105 96.3%

	Value	df	Asymp. Sig. (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	1.052 ^a	1	.305		
Continuity Correction ^b	.207	1	.649		
Likelihood Ratio	.942	1	.332		
Fisher's Exact Test				.303	.303
N of Valid Cases	109				

P value was found to be 0.303 according to Fisher's exact test. 4 members only included in this so Fisher's exact is used because for any value less than 5, this statistical method is a valid one.

**ALCOHOL DEPENDENCE AND FAMILY HISTORY OF
PSYCHIATRIC ILLNESS:**

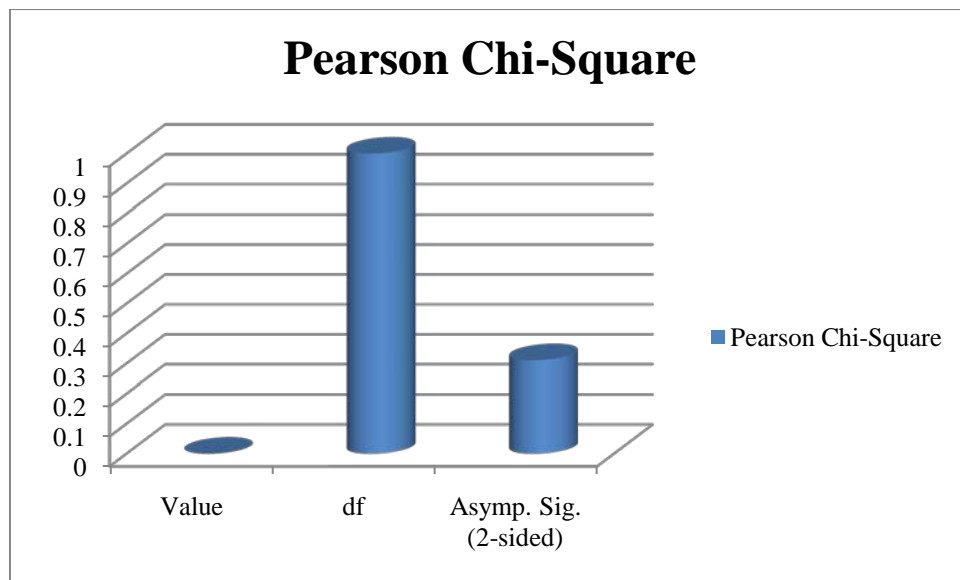
			Family history psychiatric illness		Total
			Yes	No	
ADS	N	Count	8	20	28
		% within ADS	28. 6%	71. 4%	100. 0%
	Y	Count	36	42	78
		% within ADS	46. 2%	53. 8%	100. 0%
Total	Count		44	62	106
	% within ADS		41. 5%	58. 5%	100. 0%



In Fisher's exact test, sigma 1 tailed showed value of 0. 08 and sigma 2 tailed showed value of 0. 122 which is not statistically significant. So alcohol dependence group did not have any significant association with family history of psychiatric illness.

ALCOHOL DEPENDENCE AND PRIOR TUBERCULOSIS EPISODE:

			Prior_TB		Total
			Yes	No	
ADS	N	Count	13	17	30
		% within ADS	43. 3%	56. 7%	100. 0%
	Y	Count	26	53	79
		% within ADS	32. 9%	67. 1%	100. 0%
Total	Count		39	70	109
	% within ADS		35. 8%	64. 2%	100. 0%



p value according to Pearson is 0. 311 which is not statistically significant and so no positive association between alcohol dependence syndrome and prior episode of tuberculosis.

ADS		N	Mean	P value	Standard Deviation
NOT OCCUPIED MONTHS	Yes	79	5. 595	. 438	3. 0740
TT ADHERENCE MONTHS	Yes	79	2. 1485	. 385	1. 43204
AUDIT	Yes	79	32. 05	. 000	7. 490
LAST DRINK MONTHS	Yes	79	2. 4259	. 000	6. 66458
ADS DURATION YEARS	Yes	79	13. 766	. 000	9. 9350
PRIOR TB IN YEARS	Yes	79	. 949	. 559	2. 0857
PRIOR TB ATT ADHERENCE IN MONTHS	Yes	79	1. 082	. 244	1. 7384
QUIT BEFORE	Yes	79	. 190	0. 009	1. 6876

When alcohol dependence was compared with months of unemployment, tuberculosis treatment adherence in months, prior episode of tuberculosis, prior treatment adherence in months, significant p value was not found. With AUDIT score a mean value of 32+/-SD was found and p value was significant (<0. 05), last drink in months was found to have a mean of 2. 4259+/- SD and a p value of 0. 00 was found, years of alcohol usage was found to be 13. 766+/- SD and a p value was 0. 000.

ALCOHOL DEPENDENCE VS PERSONALITY FACTORS

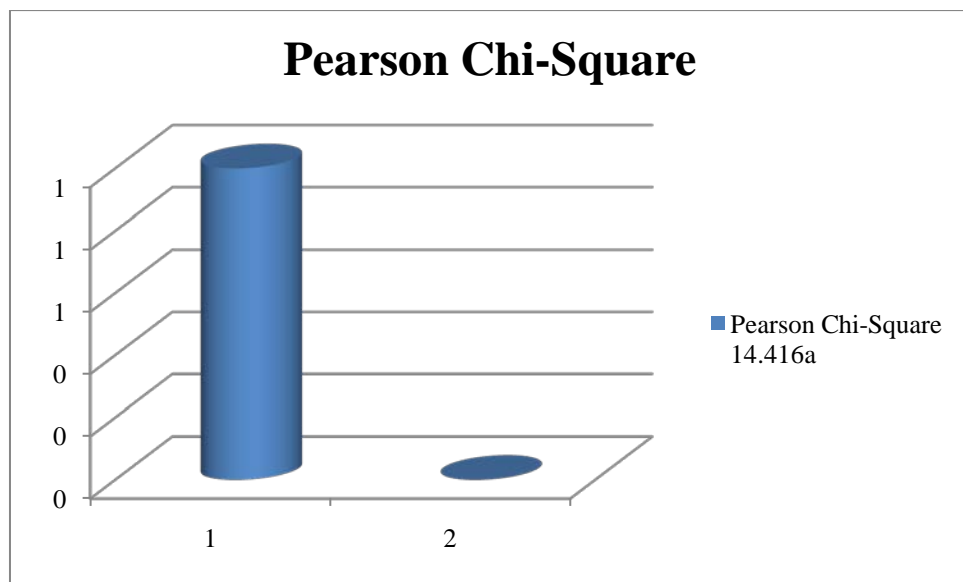
PERSONALITY FACTORS WHICH DOESNOT HAVE A

CORRELATION WITH ALCOHOL DEPENDENCE ($p>0.05$):

PERSONALITY FACTORS	P VALUE
Competence	0.183
Altruism	1.000
Self discipline	0.477
Activity	1.000
Gregariousness	0.477
Excitement	1.000
Anxiousness	0.663
Impulsivity	0.068
Assertiveness	1.000
Feelings	0.303
Depressiveness	0.491
Self-consciousness	0.560
Modesty	0.682
Aesthetics	0.477
Trust	0.477
Straightforwardness	1.000

ALCOHOL VS ANGRY HOSTILITY:

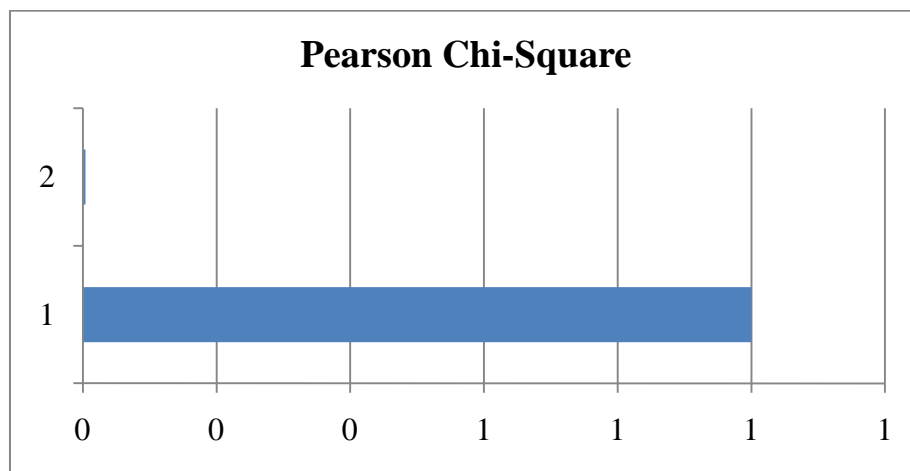
			Angry hostility		Total
			No	Yes	
ADS	No	Count % within ADS	22 73.3%	8 26.7%	30 100.0%
	Yes	Count % within ADS	26 32.9%	53 67.1%	79 100.0%
Total		Count % within ADS	48 44.0%	61 56.0%	109 100.0%



p value using pearson chi-square found to be 0. 000 and significant.

ALCOHOL DEPENDENCE VS VULNERABILITY:

			Vulnerability		Total
			No	Yes	
ADS	No	Count % within ADS	25 83.3%	5 16.7%	30 100.0%
	Yes	Count % within ADS	42 53.2%	37 46.8%	79 100.0%
Total		Count % within ADS	67 61.5%	42 38.5%	109 100.0%

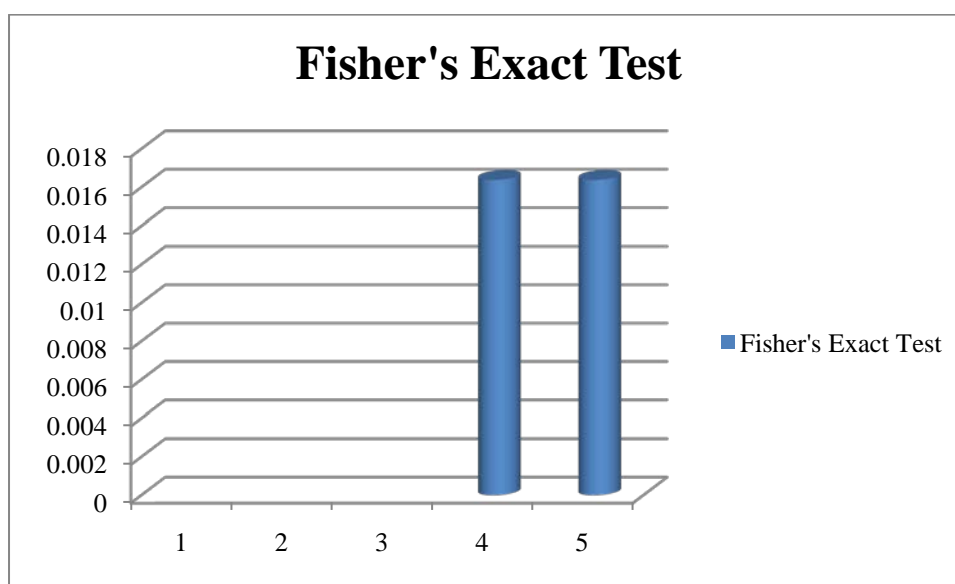


Here 2 is the p value according to pearson chi-square test which has a value of 0.004 stating that alcohol dependence has a correlation with vulnerability as a personality factor.

ALCOHOL VS VALUES

(PERMISSIVE, BROAD –MINDED)

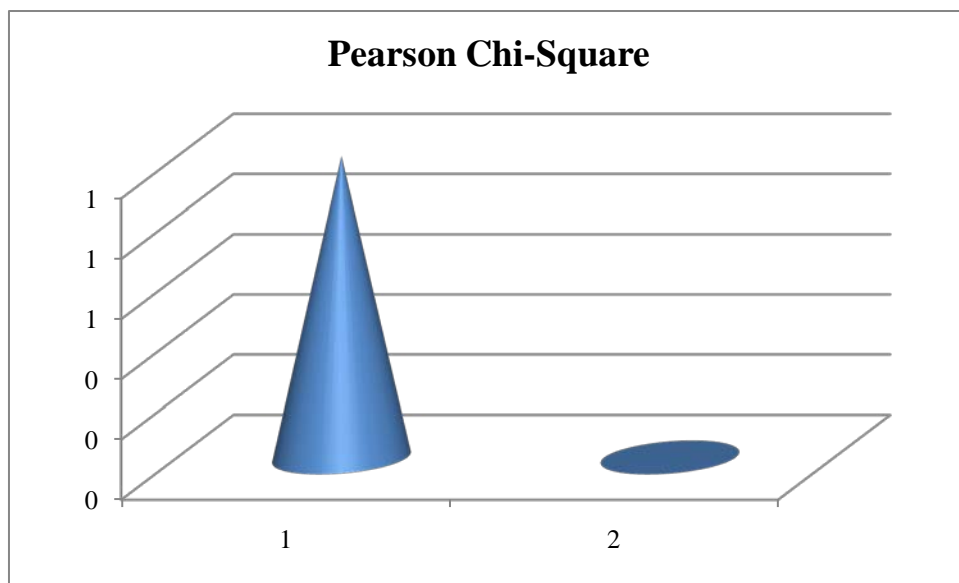
			VALUES		Total
			No	Yes	
ADS	No	Count % within ADS	25 83. 3%	5 16. 7%	30 100. 0%
	Yes	Count % within ADS	77 97. 5%	2 2. 5%	79 100. 0%
Total		Count % within ADS	102 93. 6%	7 6. 4%	109 100. 0%



p value here is 0. 01 and is statistically significant.

ALCOHOL AND TENDER MINDEDNESS

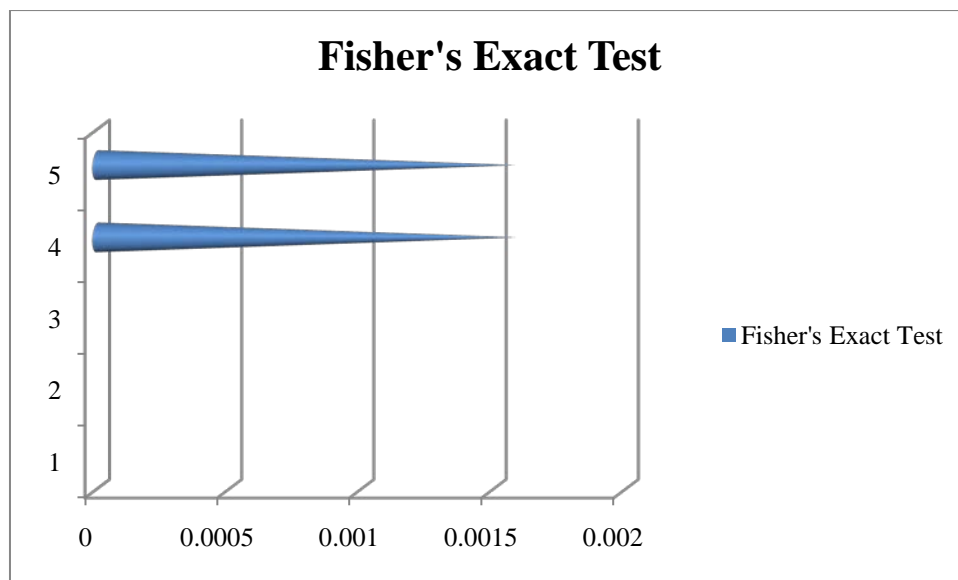
			Tendermindedness		Total
			No	Yes	
ADS	No	Count % within ADS	24 80.0%	6 20.0%	30 100.0%
	Yes	Count % within ADS	77 97.5%	2 2.5%	79 100.0%
Total		Count % within ADS	101 92.7%	8 7.3%	109 100.0%



P value is 0.002 which is significant for tender mindedness personality factor and alcohol dependence.

ALCOHOL VS COMPLIANCE (DOCILE, CO-OPERATIVE)

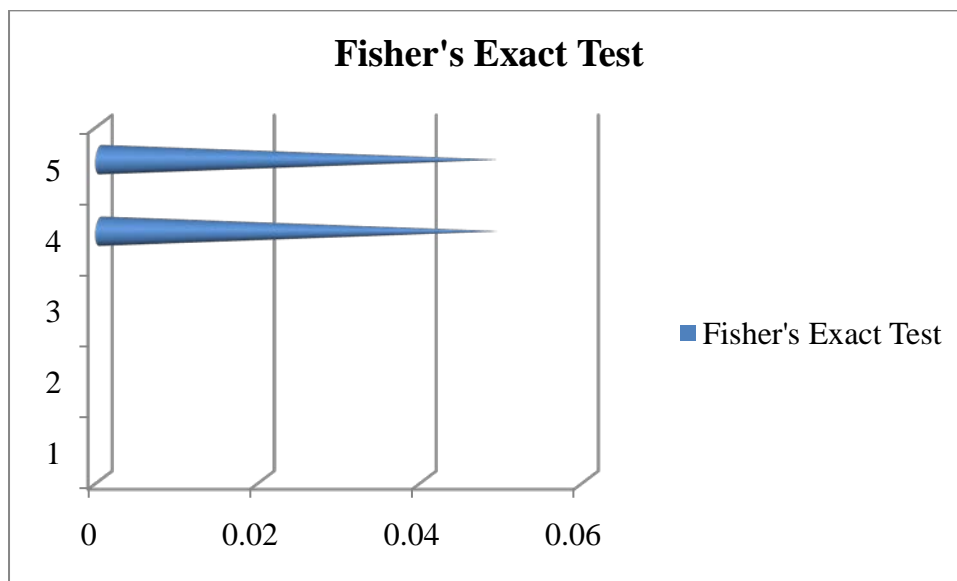
			Compliance		Total
			No	Yes	
ADS	No	Count	23	7	30
		% within ADS	76. 7%	23. 3%	100. 0%
	Yes	Count	77	2	79
		% within ADS	97. 5%	2. 5%	100. 0%
Total		Count	100	9	109
		% within ADS	91. 7%	8. 3%	100. 0%



In Fisher's exact, p value is 0. 002 which is statistically significant for the compliance factor.

ALCOHOL DEPENDENCE VS WARMTH FACTOR

			Warmth		Total
			No	Yes	
ADS	No	Count % within ADS	26 86. 7%	4 13. 3%	30 100. 0%
	Yes	Count % within ADS	76 97. 4%	2 2. 6%	78 100. 0%
Total		Count % within ADS	102 94. 4%	6 5. 6%	108 100. 0%



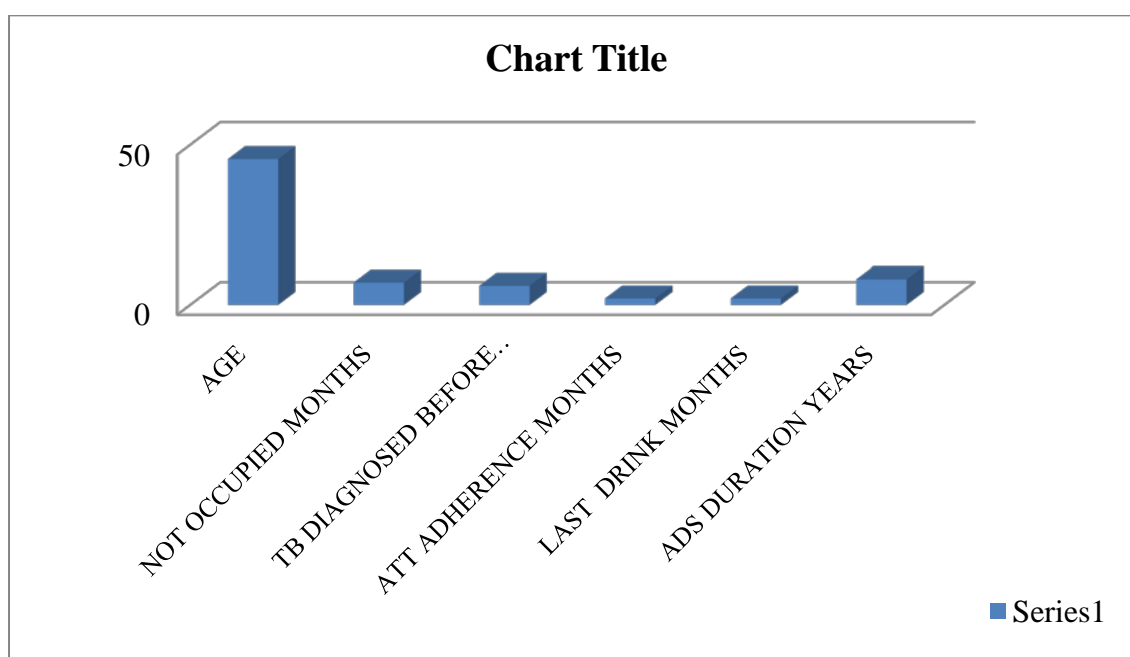
p value is significant for warmth factor (0. 04)

PSYCHIATRIC ILLNESS AND TUBERCULOSIS

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	3	2.8	2.8	2.8
AH	1	.9	.9	3.7
BPAD-1M, 1D	1	.9	.9	4.6
DEPRESSION	1	.9	.9	5.5
N	102	93.6	93.6	99.1
PANIC	1	.9	.9	100.0
Total	109	100.0	100.0	

In this sample, 4 members were found to have psychiatric illness, 1 was found to have Auditory hallucinations secondary to alcohol use, 1 patient had BPAD on drugs euthymic with YMRS score-8, 1 was found to have Panic disorder symptoms and a score of 8 in Panic Disorder Severity Scale, 1 had depression with HAMD scores 12 but was not on any drugs.

PSYCHIATRIC ILLNESS VS OTHER PARAMETERS



Mean age was found to be 45. 45+/- standard deviation, Months of unemployment in this group had a median value 7 (Range3-12), Tuberculosis

diagnosed in this group was found to be before 6 months (Range 4-6 months), ATT adherence in months found to have median value of 2 months (range 1-3 months) Last drink in months was found to have a median value 2 months (Range 0. 6-3 months) Alcohol duration in years was found to have a median value of 8 (Range 3-15 months)

PSYCHIATRIC ILLNESS VS OTHER GROUPS:

PSYCHIATRIC ILLNESS	FREQUENCY	FISHER'S EXACT (p)
ALCOHOL DEPENDENCE	2	0. 303
CMI	1	0. 520
PRIOR TUBERCULOSIS	1	1. 000
FAMILY HISTORY OF PSYCHIATRIC ILLNESS	2	1. 000

Among 4 members with psychiatric illness, 2 had alcohol dependence, 1 had co-morbid medical illness, 1 had prior history of tuberculosis but none was statistically significant as per fisher's exact test.

Psychiatric illness	N	Mean	Std. Deviation	P value
NOT OCCUPIED MONTHS Yes	4	4.500	3.8730	0.303
TB DIAGNOSED BEFORE MONTHS Yes	4	6.750	1.8930	0.555
ATT ADHERENCE MONTHS Yes	4	2.1250	1.03078	0.890
AUDIT Yes	4	28.00	18.762	0.574
LAST DRINK MONTHS Yes	4	1.5000	1.73205	0.553
ADS DURATION YEARS Yes	4	9.250	8.2209	0.761
PRIOR TB IN YEARS Yes	4	.750	1.5000	0.785
PRIOR TB ATT ADHERENCE IN MONTHS Yes	4	1.000	2.0000	0.816
QUIT BEFORE Yes	4	0.000	0.000	.605

p value was not found to be statistically significant when compared with other groups.

PREVELANCE OF PERSONALITY FACTORS:

PERSONALITY FACTORS	FREQUENCY	PERCENTAGE
Anxiousness	19	17. 5
Angry hostility	61	56
Impulsivity	59	54. 1
Vulnerability	42	38. 5
Assertiveness	16	14. 7
Feelings	4	3. 7
Values	7	6. 4
Depressiveness	11	10. 1
Self consciousness	3	2. 8
Modesty	8	7. 3
Tender Mindedness	8	7. 3
Compliance	9	8. 3
Warmth	6	6. 4
Aesthetics	2	1. 8
Trust	2	1. 8
Straightforwardness	4	3. 7
Excitement seeking	2	1. 8
Gregariousness	2	1. 8
Activity	1	0. 9
Self-discipline	2	1. 8
Altruism	1	0. 9
Competence	3	2. 7

In this study, 56% reported to have angry hostility, 54. 1% found to have Impulsivity, 38. 5% had vulnerability, 17. 5% members reported to have anxiousness, 14. 7% found to have assertiveness and 10. 1% reported that they had depressiveness, least reported factors were activity which included energy, active. It was reported by 0. 9% of the members only.

DISCUSSION

Aim of this study was to study the prevalence of psychiatric illness, alcohol abuse and personality factors among tuberculosis default patients and to study the role of these factors in anti tuberculosis drug discontinuation.

RESULTS IN DEMOGRAPHIC PROFILE

In this 110 sample, regarding sex, majority were males (94. 5%) The lesser percentage in females is an indirect indicator of stigma which in accordance with the previous study by Dhingra et al²⁹ which shows that stigma is high among females which leads to poor drug adherence. Nearly 53% had their income more than 2000 rupees. In terms of education, 21% were illiterates and only 5. 5% were found to have completed college degree. Nearly 5. 5% of the patients reported from the areas Villivakkam and Otteri where tuberculosis hospital was located and this high default in the same area is again an indirect indicator of poor knowledge regarding drug intake and stigma associated with the illness which prevents the patients from adherence.

About 90% of the population enrolled were married which indicates a good social support, also majority belonged to Hinduism (92%)Co morbid illnesses were not found in 90% of the population and this might again explain the reason for not seeking medical attention. 6. 4% reported to have Diabetes Mellitus which suppress the immune system further leading to high chances of relapse and treatment failure followed by Systemic Hypertension (2. 8%) and only 2 had Decompensated Liver Disease.

In this sample, 14. 3% had a family history of Alcohol dependence syndrome in their father followed by 2. 4% alcohol dependence in their elder brother explaining a genetic vulnerability for substance dependence which further complicates treatment adherence. Regarding co-morbid substance use, beedi smoking was found in 10. 1% and both beedi and cigarette smoking was found in 14. 7% of the sample.

Mean age was found to be 45 years. Number of months not occupied was found to have a median value of 7 months indicating social and functional impairment. Tuberculosis diagnosed in months was found to have a median value of 6 months and this minimizes the recall bias regarding discontinuation of the drug. Anti tuberculosis drug adherence was found to have median value of 2 months which is again in accordance with the previous studies which proves that patients tend to discontinue anti-tuberculosis drugs soon after the intensive phase and this is in accordance with a previous study by Jessica et al⁴³ which states that defaulters were found to be more during the initial continuation phase as they tend to feel better with drugs soon after they complete the intensive phase. This again confirms the findings by Beena Thomas et al¹³⁷ which says that after starting to consume alcohol, due to fear of re-visiting the health care professionals, patients tend to discontinue the medications. Last drink in this sample was found to be 2 months back denoting a highly prevelant dependence pattern and Alcohol dependence syndrome in years was found to have median value of 8 years in this sample and this group

exhibited pattern of daily consumption of alcohol which as per Fathima et al¹⁵⁹ has a very poor drug adherence and adverse outcome.

ALCOHOL DEPENDENCE SYNDROME AND OTHER PARAMETERS

79 members (72. 5%) reported alcohol dependence syndrome in this sample and had AUDIT score above 8. This particular percentage is very high when compared with the previous studies like Jakuboviak et al³⁸ which showed 47% and Patel et al ⁴⁹ study which showed a 20-30% prevalence of alcohol dependence syndrome among tuberculosis patients in developing countries. 59 members had score more than 30 necessitating the need for intervention in this group as highlighted by Shin et al¹⁶⁵ which put forth the role of both pharmacological management like naltrexone as well as behavior modification like counseling to increase the motivation of the patients to improve adherence.

64 members stated that their alcohol habit was the reason for them to discontinue tuberculosis drugs and the result in this study is very high when compared with the Muture et al¹⁸⁰ study which was chosen for sample calculation which quoted only 7. 5% of alcohol dependence syndrome as a reason for default.

Among the 79 members with alcohol dependence, 48 had income less than 2000 rupees with a significant p value which indicates an association between alcoholism and lack of employment and poor financial status and this confirms the results of Garfein et al²¹ which put forth overcrowding and homelessness results in very high chances of default and relapse rates.

In this study, significant association could not be established when alcohol dependence syndrome was compared with parameters like family history of psychiatric illness, co-morbid psychiatric illness, prior attack of tuberculosis, drug adherence during prior attack of tuberculosis and this finding is a deviation from the previous studies like

Karthikeyan Duraisamy et al¹⁸ which states that among defaulters, those with alcohol consumption was found to miss more than 7 intensive phase doses and on average about 18 when compared with patients who do not drink alcohol.

Alcohol dependence syndrome was found to have a positive association with AUDIT score and mean was found to be 32 which shows more than a mere dependence pattern and this is in accordance with Baski et al¹⁶⁰ study which states that persons who had 3 more drinks daily were heavy drinkers and were twice at risk of developing tuberculosis than non-heavy drinkers. This result also proves the validity of AUDIT scale which gives a cut off for score more than 8 and necessitates the need for intervention in this sample, and it has got a mean value of 32. This is again in accordance with the previous studies like Imtiaz et al¹⁶⁸ which also highlights the need to find out the alcohol use pattern based on which management can be planned.

Alcohol dependence had a positive correlation with the last drink which has a value of 2 months in this study which indicates that many had their last drink within past 2 months when they were in treatment. Samai Laprawat et

al¹³⁶ says that patients who stop alcohol during treatment succumb back within 3-4 months once their general condition improves and the same finding is replicated in this study also because at the end of intensive phase of treatment many feel that their physical condition has improved and succumb to their drinking habits and another pattern of alcoholism is also described in this study where the patients continue to use alcohol inspite of tuberculosis medications which has a still more adverse outcome.

The total duration of alcohol dependence pattern in this study was found to be 13 years which indicates that majority were drinking over a period of more than 13 years.

ALCOHOL DEPENDENCE AND PERSONALITY FACTORS:

Personality factors which does not have positive correlation with alcohol dependence are self discipline, activity, gregariousness, excitement, anxiousness, impulsivity, assertiveness, feelings, depressiveness, self-consciousness, modesty, aesthetics, trust, straight forwardness, competence, altruism. This implies that patients with alcohol dependence reported the above mentioned factors only to a lesser extent and also that chances of alcohol co-existing with the above mentioned personality factors is meager.

Factors which got a positive correlation with alcohol and a significant p value are angry hostility, vulnerability, permissive and broad mindedness values, tender mindedness, compliance. This replicates the results of studies done Choudary et al²⁰ which says that traits of neuroticism, over protectiveness

and lability were highly prevalent among default patients and nearly 52% had neurotic traits which had high default rates and at the same time it was amenable to behavior modification.

PSYCHIATRIC ILLNESS:

In this sample, 4 members were found to have psychiatric illness. 1 had auditory hallucinations alone secondary to alcohol use and 1 had depression with HAMD score 12. This is not in accordance with the previous studies by Francis et al³⁶ which gives a 42% of depression among defaulters. Also cough as an independent risk factor for depression as stated by French et al¹¹² and 80% prevalence of depression as stated by Muhammad Anwar et al¹¹⁸ is not being found in our study results. 1 was found to have a panic disorder with a score of 8 in Panic Disorder Severity Scale. Chand et al⁶⁶ found an association between panic disorder and tuberculous meningitis which was not established in our study as co existing neurological manifestations were excluded in our study.

1 patient who had 1 previous episode of mania and depression currently with YMRS scores-8 and under remission is reported in our study. Median value of 7 months of unemployment was found in this group, Tuberculosis diagnosed in this group was found to be before 6 months, ATT adherence in months found to have median value of 2 months which is again an indicator that majority tend to discontinue the drugs at the end of intensive phase. Last drink in months was found to have a median value 2 months. Alcohol duration in years was found to have a median value of 8 years.

Significant association could not be established between psychiatric illness and alcohol dependence, co-morbid illness, prior episode of tuberculosis, family history of psychiatric illness, months of unemployment, AUDIT scores, ATT adherence in months, alcohol use in years because only 4 of them reported to have psychiatric illness. As only 4 among the sample reported psychiatric illness, relationship between psychiatric illness and various personality factors could not be assessed in this study.

PERSONALITY FACTORS

Angry hostility and impulsivity are the dominant personality factor traits in this study and the positive correlation between alcohol dependence with these factors again confirms the predominance of these 2 factors among defaulters and their role in drug adherence. Vulnerability, anxiousness, assertiveness and depressiveness are the next predominant factors in this population and this is in accordance with the results of previous studies by Immerman et al¹⁷⁶ which have also highlighted the predominance of neurotic traits which were not controlled by the anti-tuberculosis medications and this study highlights the inclusion of psychotherapy to modify the personality factors to improve adherence. Our study findings also replicate the results of Bansal et al¹⁷⁴ which states that among 214 participants, 54. 1% were found to be anxious personality when assessed with 16-Personality Questionnaire.

CONCLUSION

In this study 79 members reported to abuse alcohol daily having a dependent pattern and nearly 64 stated alcohol as the reason for them to discontinue anti tuberculosis medications and this percentage is high when compared with the previously mentioned studies which give only less than 30%. This shows a high prevalence of alcohol dependence among tuberculosis default patients and also that alcohol is an independent risk factor for 64 members in this study to discontinue anti –tuberculosis medications which disproves our null hypothesis which states that there is no correlation between alcohol use and discontinuation of anti tuberculosis medications. But psychiatric illness was reported only by 4 people in this study which is less when compared with the previous studies where previous ones have quoted a high prevalence of depression among tuberculosis patients. Hence our null hypothesis stating no association between psychiatric illness and tuberculosis drug adherence is proved true. Regarding personality factors, angry, vulnerability, anxiousness, assertiveness, depressiveness and impulsivity were found to be highly prevalent among the defaulter groups and it also had a positive correlation with alcohol use which states that patients with these factors are highly prone for poor drug adherence which again disproves our null hypothesis. This also implies that these groups can be considered as high risk and to be screened during the commencement of the treatment in order to prevent default and relapse. Significant association between personality factors and psychiatric illness could not be established in this study as only 4 were

found to have illness. Significant association between alcohol dependence, last drink and AUDIT scores were also found in this study and thus highlighting the need for intervention to improve adherence and to prevent further default or relapse.

STRENGTH OF THE STUDY

1. The study was conducted in a tertiary care hospital with good maintenance of records regarding the drug adherence.
2. Standard screening module and scales with high reliability were enrolled in this study.
3. Diagnosis of tuberculosis were made within the past 6 months which reduced the recall bias regarding details of drug discontinuation.

LIMITATIONS OF THE STUDY

- 1) This study is a cross sectional study done at one time.
- 2) The study population in this group belonged to low socio economic status with lower level of education and so results cannot be generalized to the population.
- 3) Sample size is small. Larger sampling is required for refined analysis.

FUTURE DIRECTIONS

- 1) This study can be conducted with control groups so that the role of these factors can be analyzed with more clarity and by doing so, there appears higher chances of generalizing the results.
- 2) Longitudinal study pattern conducted throughout the 6 months period can throw light over the individual role of all these factors in drug adherence and default.
- 3) Apart from screening and diagnosing, intervention at various levels with both drugs as well as psychotherapy can be included to assess the response and improvement in adherence.

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Structured Clinical Interview for DSM-IV Axis I Disorders

Patient Edition (February 1996 FINAL)
SCID-I/P (Version 2.0)

Overview

INTERVIEW INFORMATION

Status: ☐ In progress ☐ Completed ☐ Consensus reviewed

Type: ☐ Computer ☐ Paper

Subject ID:

Subject Initials:

Rater:

Site:

Date of Interview:

Sources of information ☐ Subject

(check all that apply):

☐ Family

☐ Health professional/chart/referral note

Relationship to Proband:

Edited and checked by:

Date:

Recruitment Source:

DEMOGRAPHIC DATA

I'm going to be asking you about problems or difficulties you may have had, and I'll be making some notes as we go along. Do you have any questions before we begin?

Information

Gender: Date of Birth: Age:

What do you consider to be your ethnic origin?

Marital Status

What is your current marital status?

Dates of Marriage

Start Date End Date Comments

Children

Do you have any children? ☐ Yes ☐ No

Children

Gender Age Comments

Living Situation

With whom do you live?

Religion

What was your childhood religious affiliation, if any?

What is your current religion, if any?

FAMILY HISTORY

Were you adopted? ☐ Yes ☐ No

Mother

Living: ☐ Yes ☐ No

Brief Description (age, current location and living situation, general disposition, etc):

Occupation:

Highest Level of Education:

Religion:

of Siblings:

Father

Living: ☐ Yes ☐ No

Brief Description (age, current location and living situation, general disposition, etc):

Occupation:

Highest Level of Education:

Religion:

of Siblings:

Do you have any siblings? ☐ Yes ☐ No

(If yes, note genders and ages. Also indicate half of step siblings.)

Are you close to any of your siblings?

What was it like growing up in your family?

(Briefly describe home environment and relationships, including any trauma or abuse.)

Family History Form

Interviewer: "Tell me about your biological parents, children, siblings and grandparents." Ask if they have had any problems with their mood or anxiety or problems with drugs or alcohol. If adopted, ask about biological family; if not known, indicate "Adoptive Family" and answer accordingly. If deceased, note both date of death and "+" symbol in current age column.

Relation	Name	Current Age	Psychiatric Symptoms	Professional Diagnosis (list)	Psychiatric Treatment	Comments

DEVELOPMENTAL HISTORY

Where were you born and raised?

(Significant moves, health, school, friends, activities, etc.)

EDUCATION

How far did you get in school?

EVER FAILED TO COMPLETE A PROGRAM IN WHICH S/HE WAS ENROLLED: Why didn't you finish?

MILITARY HISTORY

Military Service: ☐ Yes ☐ No

Branch:

Start of Service:

End of Service:

Veteran:

☐ Yes ☐ No

Theater:

Combat:

☐ Yes ☐ No

Type of Discharge:

Rank at Discharge:

MOS:

Service Connected
Disability

☐ Yes ☐ No

Percent

Reason

WORK HISTORY

Are you working now? What is your job? How long have you been there?

[IF LESS THAN 6 MONTHS: Why did you leave your last job?]

Have you always done this kind of work? [IF NOT: What kind of work have you done?] What is the highest level job you have ever held? [Chronology of work history: (include longest job held and longest time unemployed)] How are you supporting yourself now? (If disability, list type, date and reason.)

Has there ever been a period of time when you were unable to work or go to school? (When? Why was that?)

OVERVIEW OF PRESENT ILLNESS

Have you been in any kind of treatment in the past month?

[IF CURRENTLY IN TREATMENT:

Date of admission to inpatient or outpatient facility.]

CHIEF COMPLAINT

(Description of presenting problem): [RECORD DIRECT QUOTE]

What led to your coming here? What is the major problem you have been having?

HISTORY OF PRESENT ILLNESS

Do you currently have any psychiatric symptoms or emotional problems? ☐ Yes ☐ No

IF YES: When did your current symptoms begin? When were you last feeling your normal self? Is this something new or a return of something you have had before? What was going on in your life when this began? (Environmental context for precipitants of present illness or exacerbation) Did anything happen or change? Since this began, when have you felt the worst? (IF MORE THAN A YEAR AGO: In the last year, when have you felt the worst?)

Have you had any other problems in the last month? What has your mood been like? How have you been spending your free time? Who do you spend time with?

How much have you been drinking (alcohol) (in the past month)? Have you been taking any drugs (in the past month)? (What about marijuana, cocaine, other street drugs?)

PAST PSYCHIATRIC HISTORY

When in your life did you first experience your symptoms? When was the first time you saw someone for emotional or psychiatric problems? (What was that for? What treatment(s) did you receive? What medications?) Were there other times when you had counseling or treatment of any kind? (What type? When?)

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Age of first treatment for Depression

Age of first treatment for Mania

Age of first treatment for Hypomania

Age of first treatment for Mixed State

Age of first treatment for Psychosis/SZ

HOSPITALIZATIONS:

Have you ever been a patient in a psychiatric hospital?

☐ Yes ☐ No

(IF YES: When? Where? Why?)

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Number of previous hospitalizations for Depression

(Do not include transfers)

Number of previous hospitalizations for Mania

Number of previous hospitalizations for Mixed State

Number of previous hospitalizations for Non-mood

Estimated lifetime total time of psychiatric hospitalization in weeks:

--

SUBSTANCE/ALCOHOL TREATMENT:

Have you ever had treatment for drugs or alcohol?

☐ Yes ☐ No

Treatment Information:

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ATTENTION DEFICIT-HYPERACTIVITY DISORDER:

Have you ever been diagnosed with Attention Deficit-Hyperactivity Disorder?

☐ Yes ☐ No

(Include symptoms, presentation, age at diagnosis, age of first symptoms and treatment)

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Medication Assessment Form

Category: Class: Drug Name: Start Date: End Date: ☐ Unknown

Multiple Trials:	Duration Used:	Reason Stopped:	Response Type:	Treatment Induced:

Comments

[Record side effect information whenever possible.]

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MEDICAL HISTORY

Have you had any medical problems now or in the past? (What were they? How were they treated?) Were you ever in the hospital for treatment of a medical problem? (What was that for?) Have you ever had any surgeries (including outpatient)? (When? What were they for?)

☐ Yes ☐ No

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ALLERGIES:

Do you have any allergies? To Medications? Other?

☐ Yes ☐ No

GENETIC DISORDERS:

Do you have any other genetic disorders? (What and when diagnosed?) Do you know of any genetic disorders that run in your family? (What? Who?)

☐ Yes ☐ No

THYROID DISORDER:

Have you ever been treated for a thyroid disorder? (Include diagnosis, age of diagnosis, and treatment) Was this only while on Lithium?

☐ Yes ☐ No

HEAD INJURY:

Have you ever had a head injury? (Did you lose consciousness? How long? How many times have you lost consciousness due to a head injury?)

☐ Yes ☐ No

FEMALES ONLY:

Have you gone through menopause? (Have you ever had any serious emotional problems associated with menopause?)

☐ Yes ☐ No

OTHER CURRENT PROBLEMS

MOST LIKELY CURRENT DIAGNOSIS

DIAGNOSES THAT NEED TO BE RULED OUT

GLOBAL ASSESSMENT OF FUNCTIONING

Current GAF

DSM-IV Axis V: Global Assessment of Functioning Scale

Consider psychological, social, and occupational functioning on a hypothetical continuum of mental health-illness. Do not include impairment in functioning due to physical (or environmental) limitations. Indicate appropriate code for the LOWEST level of functioning during the week of POOREST functioning. (Use intermediate level when appropriate, e.g., 45, 58, 72.)

- | | |
|-----|--|
| 100 | Superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his or her many positive qualities. No symptoms. |
| 91 | |
| 90 | Absent or minimal symptoms (e.g., mild anxiety before an exam), good functioning in all areas, interested and involved in a wide range of activities, socially effective, generally satisfied with life, no more than everyday problems or concerns (e.g., an occasional |

81 argument with family members).

80 If symptoms are present, they are transient and expectable reactions to psychosocial stressors (e.g., difficulty concentrating after
71 family argument), no more than slight impairment in social, occupational, or school functioning (e.g., temporarily falling behind in
school work).

70 Some mild symptoms (e.g., depressed mood and mild Insomnia) OR some difficulty in social, occupational, or school functioning
61 (e.g., occasional truancy, or theft within the household), but generally functioning pretty well, has some meaningful interpersonal
relationships.

60 Moderate symptoms (e.g., flat affect and circumstantial speech, occasional panic attacks) OR moderate difficulty in social,
51 occupational, or school functioning (e.g., few friends, conflicts with co-workers).

50 Serious symptoms (e.g., suicidal ideation, severe obsessional rituals, frequent shoplifting) OR any serious impairment in social,
41 occupational, or school functioning (e.g., no friends, unable to keep a job).

40 Some impairment in reality testing or communication (e.g., speech is at times illogical, obscure, or irrelevant) OR major impairment
31 in several areas, such as work or school, family relations, judgment, thinking, or mood (e.g., depressed man avoids friends, neglects
family, and is unable to work; child frequently beats up younger children, is defiant at home, and is failing at school).

30 Behavior is considerably influenced by delusions or hallucinations OR serious impairment in communication or judgment (e.g.,
21 sometimes Incoherent, acts grossly inappropriately, suicidal preoccupation) OR inability to function in almost all areas (e.g., stays in
bed all day; no job, home, or friends)

20 Some danger of hurting self or others (e.g., suicide attempts without clear expectation of death, frequently violent, manic excitement)
11 OR occasionally fails to maintain minimal personal hygiene (e.g., smears feces) OR gross impairment in communication (e.g.,
largely incoherent or mute)

10 Persistent danger of severely hurting self or others (e.g., recurrent violence) OR persistent inability to maintain minimal personal
1 hygiene OR serious suicide act with clear expectation of death

INFORMATION TO PARTICIPANTS

Title: A STUDY ON PREVALENCE OF PSYCHIATRIC CO-MORBIDITY, ALCOHOL ABUSE, PERSONALITY FACTORS IN TUBERCULOSIS DEFAULT PATIENTS

Principal Investigator: Dr. Vishnu Priya.v

Name of Participant:

Site: Government Thiruvoteeswarar Tuberculosis Hospital, Otteri, Chennai

You are invited to take part in this research. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

What is the purpose of research.

Tuberculosis is a chronic debilitating illness especially in countries like India. Drug adherence is very important in this illness. Poor adherence results in increased chances of default, relapse and drug resistance. We want to assess the Prevalence of psychiatric co-morbidity, alcohol abuse, personality factors in tuberculosis default patients

We have obtained permission from the Institutional Ethics Committee.

The study design and procedures:

20 - 60 years aged in patients admitted and diagnosed as lost to follow up or default are enrolled in this study. The following scales are given to them in one setting.

The instruments used are:

☐ SCID-Structured Clinical Interview in DSM-5

. PDSS-Panic disorder severity scale

☐ Hamilton's depression rating scale.

☐ Young mania rating scale.

☐ Alcohol use disorder identification test (AUDIT)

5 Factor Personality Self Rating Form

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Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, Institutional Ethics Committee and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

How will your decision to not participate in the study affect you?

Your decision not to participate in this research study will not affect your medical care or your relationship with the investigator or the institution. You will be taken care of and you will not lose any benefits to which you are entitled.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during the course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to discontinuing from the study.

Signature of Investigator Signature of Participant

Signature of the Guardian

Date

INFORMED CONSENT FORM

(This is only a guideline – Relevant changes to be made as per the study requirements)

Title of the study: “A STUDY ON PREVALENCE OF PSYCHIATRIC CO-MORBIDITY,ALCOHOL ABUSE,PERSONALITY FACTORS IN TUBERCULOSIS DEFAULT PATIENTS”.

Name of the Participant:

_____.

Name of the Principal (Co-Investigator): _Dr. Vishnu Priya. V

Name of the Institution:Government Thiruvoteeswarar tuberculosis hospital, Otteri, Chennai

_____.

Name and address of the sponsor / agency (ies) (if any):__No_____

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in

“A STUDY ON PREVALENCE OF PSYCHIATRIC CO-MORBIDITY, ALCOHOL ABUSE, PERSONALITY FACTORS IN TUBERCULOSIS DEFAULT PATIENTS”.

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.
5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.
6. I have been advised about the risks associated with my participation in this study.*

7. I have not participated in any research study within the past _____month(s). *

8. I have not donated blood within the past _____ months—Add if the study involves extensive blood sampling. *

9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital. *

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent. *

11. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

12. I have understand that my identity will be kept confidential if my data are publicly presented

13. I have had my questions answered to my satisfaction.

14. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature_____

Date_____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature _____

Date _____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature _____

Date _____

Name and Signature of the investigator or his representative obtaining consent :

Name _____ Signature _____

Date _____

ஆராய்ச்சி ஒப்புதல் படிவம்

தலைப்பு : காசநோய் இயல்பு நிலை நோயாளிகளின் மன நோய், மது அருந்துதல், ஆளுமைகாரணிகள் பற்றி அறியும் - ஓர் ஆய்வு.

ஆய்வாளரின் பெயர் : மரு.வீ.விஷ்ணுபிரியா

பங்கு பெறும் இடம் : திருவொட்டிஸ்வரர் அரசு காச நோய் மருத்துவமனை, ஓட்டேரி, சென்னை

நான் இந்த படிவத்தை முழுமையாக படித்தேன். சந்தேகங்களை கேட்டு தெளிவுபடுத்திக் கொண்டேன். தயக்கமில்லாமல் நான் 18 வயதிற்கு மேற்பட்டவர் என்பதையும் இந்த ஆய்வாளர் மேற்கொள்ளும் காசநோய் இயல்பு நிலை நோயாளிகளின் மன நோய், மது அருந்துதல், ஆளுமைகாரணிகள் பற்றி அறியும் - ஓர் ஆய்வு இதில் என்னை இணைத்துக் கொள்ள முழு சம்மதம் தெரிவிக்கிறேன்.

1. நான் இந்த ஒப்புதல் படிவத்தில் உள்ள அனைத்தையும் படித்து அறிந்துக் கொண்டேன்.
2. ஒப்புதல் படிவம் முழுவதுமாக விவரிக்கப்பட்டது.
3. இந்த ஆய்வின் தன்மையை பற்றிய விவரங்கள் அறிந்துக் கொண்டேன்.
4. என்னுடைய உரிமைகளையும் மற்றும் பொறுப்புகள் என்ன என்பதையும் ஆய்வாளர் மூலம் அறிந்துக் கொண்டேன்.
5. நான் முன்பு எடுத்துக் கொண்ட எல்லா சிகிச்சை முறைகளையும் ஆய்வாளருக்கு தெரியப்படுத்தினேன்.
6. இந்த ஆய்வின் நான் பங்கு பெறுவதின் மூலம் ஏற்படும் விளைவுகளையும் நான் அறிந்துக் கொண்டேன்.
7. நான் ஆய்வாளருக்கு என் முழு ஒத்துழைப்பும் அளிப்பேன். மேலும் எனக்கு ஏதேனும் வித்தியாசமான அறிகுறிகள் தென்பட்டால் அதை உடனே ஆய்வாளருக்கு தெரிவிப்பேன்.
8. நான் இந்த முன்பு கடந்த மாதங்களில் எந்தவித ஆய்வுகளிலும் பங்கு பெறவில்லை.
9. நான் எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து வெளியேராலாம் என்றும் இதனால் பிற்காலத்தில் எனக்கு மருத்துமனையில் கொடுக்கப்படும் சிகிச்சையில் எந்த பாதிப்பும் ஏற்படாது என்பதை அறிந்துள்ளேன்.

10. மேலும் எந்த நேரத்திலும் எந்த காரணத்திற்காவது ஆய்வாளர் இந்த ஆய்வின் பங்காளராய் இருப்பதிலிருந்து என்னை நீக்கலாம் என்பதையும் அறிந்துள்ளேன்.
11. என்னிடம் இந்த ஆய்வின் மூலம் பெறப்பட்ட தகவல்களை ஆய்வாளர், உயர் அதிகாரிகள் மற்றும் நெறிமுறை குழுவில் தெரியப்படுத்த சம்மதிக்கிறேன். அவர்கள் என்னுடைய முழு தகவல்களை ஆராய நேரலாம் என்று அறிந்துக் கொள்கிறேன்.
12. என்னுடைய தகவல்களை வெளியிடும்பொழுது, என்னுடைய அடையாளங்கள் இரகசியமாக பாதுகாக்கப்படும் என்று அறிந்துக்கொள்கிறேன்.
13. நான் தானாகவே முன் வந்து இந்த ஆய்வில் என்னை ஒரு உறுப்பினராக இணைத்துக் கொள்கிறேன்.

இந்த ஆய்வில் எனக்கு கேள்விகள் எழுந்தால் அதை ஆய்வாளரிடம் கேட்டு அறிந்து கொள்ள வேண்டும் என்பதையும் தெரிந்துக் கொண்டேன். இந்த படிவத்தில் கையெழுத்து இடுவதன் மூலம் இந்த ஆய்வின் எல்லா கருத்துகளையும் நான் படித்து அறிந்துக் கொண்டேன் என்பதையும் தெரிவித்துக் கொள்கிறேன். இந்த படிவத்தின் நகலையும் நான் பெற்றுக் கொண்டேன்.

பங்கு பெறுபவரின் கையொப்பம் அல்லது கைரேகை

பெயர் கையொப்பம்தேதி

நடுநிலை சாட்சியாளரின் பெயர் மற்றும் கையொப்பம்

பெயர் கையொப்பம்தேதி

முகவரி தொலைபேசி எண்

ஆய்வாளரின் பெயர் மற்றும் கையொப்பம்

பெயர் கையொப்பம்தேதி

ஆராய்ச்சி ஒப்புதல் படிவம்

தலைப்பு : காசநோய் இயல்பு நிலை நோயாளிகளின் மன நோய், மது அருந்துதல், ஆளுமைகாரணிகள் பற்றி அறியும் - ஓர் ஆய்வு.

ஆய்வாளரின் பெயர் : மரு.வீ.விஷ்ணுபிரியா

பங்கு கொள்பவரின் பெயர் :

பங்கு பெறும் இடம் : திருவொட்டிஸ்வரர் அரசு காச நோய் மருத்துவமனை, ஒட்டேரி, சென்னை

ஆராய்ச்சியின் நோக்கம் :

காசநோய் என்பது வீரியம் நிறைந்த நாள்பட்டு காணப்படும் நோயாகும். மருந்து கடைப்பிடித்தல் என்பது காசநோய் மருத்துவத்தில் இன்றியமையாத பகுதியாகும். மருந்து கடைபிடிக்காவில் நோய் இயல்பு நிலை, நோய் மறுபடியும் ஏற்படும் வாய்ப்பு, மற்றும் மருந்து எதிர்ப்பு உருவாகும். ஆகவே காசநோய் இயல்பு நிலை நோயாளிகளின் மன நோய், மது அருந்துதல், ஆளுமைகாரணிகள் பற்றிய இந்த ஆய்வு. இந்த ஆய்வு நடத்த நெறிமுறை குழுவினரிடம் அனுமதி பெற்றுள்ளேன்.

ஆராய்ச்சி படிக்கும் விதம் மற்றும் செயல்முறை

20 முதல் 60 வயது வரையுள்ள 110 உள் நோயாளிகள் இந்த ஆராய்ச்சியில் இணைக்கப்பட்டு, கீழ்க்காணும் அளவீடுகள் வினா தொகுப்புகள் கேட்டு அளவிடப்படும்.

1. மது தவறான பயன்பாடு கண்டுபிடிக்கும் சூழ்நிலை
2. ஹாமில்டன் மன அழுத்த அளவீடு
3. பித்த அளவீடு
4. டி.எஸ்.எம். நான்கின் கட்டமைக்கப்பட்ட மருத்துவ நோக்காணல்
5. பீதி சீர்குலைவு தீவிரம் பற்றி அறியும் அளவீடு
6. ஐந்து ஆளுமை காரணிகள் பற்றி அறியும் சுயமதிப்பீட்டு அளவீடு

இவை எல்லாவற்றிற்கும் 45 நிமிடம் முதல் 1 மணி நேரம் ஆகலாம். இவை அனைத்தும் ஒரு தடவையிலேயே எடுக்கப்படும்.

தகவல் - ரகசிய தன்மை

இந்த ஆராய்ச்சியில் உங்களை பற்றிய தகவல்கள் (பெயர், அடையாளங்கள், மருத்துவ சோதனை, மருத்துவ விவரங்களை) வெளியிடமாட்டோம். இந்த படிவத்தில் கையெழுத்து போடுவதின் மூலம் ஆராய்ச்சியாளர்கள் அவரது குழுவினர் மற்றும் நெறிமுறை குழுவினர்கள் உங்களை பற்றிய தகவல்களை அறிந்து கொள்ளலாம் என்று ஒப்புதல் அளிக்கிறீர்கள். மேலும் இந்த ஆய்வின் அறிவியல் பத்திரிக்கைகளில் வெளியிடும் போது உங்களின் விவரங்களை வெளிப்படுத்த மாட்டோம்.

ஆராய்ச்சியில் பங்கு பெறாமல் இருந்தால் உங்களை பாதிக்குமா ?

நீங்கள் உங்களை இந்த ஆராய்ச்சியில் உட்படுத்தாமல் இருந்தாலும் மருத்து சிகிச்சையிலோ அல்லது ஆய்வாளரின் நல்லுறவிலோ எவ்வித பாதிப்பும் ஏற்படாது.

எப்பொழுது ஆராய்ச்சியிலிருந்து விடுபடுவது

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்த நேரமும் இந்த ஆராய்ச்சியிலிருந்து எந்த காரணத்திற்காகவும் விலகிக் கொள்ளலாம். ஆனால் விலகுவதற்கு முன் ஆராய்ச்சியாளருக்கு அறிவிப்பது நல்லது.

ஆராய்ச்சியாளர் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்

நாள் :

இடது கைரேகை

இடம் :

AUDIT

Introduction

The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening tool developed by the World Health Organization (WHO) to assess alcohol consumption, drinking behaviors, and alcohol-related problems. Both a clinician-administered version (page 1) and a self-report version of the AUDIT (page 2) are provided. Patients should be encouraged to answer the AUDIT questions in terms of standard drinks. A chart illustrating the approximate number of standard drinks in different alcohol beverages is included for reference. A score of 8 or more is considered to indicate hazardous or harmful alcohol use. The AUDIT has been validated across genders and in a wide range of racial/ethnic groups and is well-suited for use in primary care settings. Detailed guidelines about use of the AUDIT have been published by the WHO and are available online: http://whqlibdoc.who.int/hq/2001/who_msd_msb_01.6a.pdf

The Alcohol Use Disorders Identification Test: Interview Version

Read questions as written. Record answers carefully. Begin the AUDIT by saying "Now I am going to ask you some questions about your use of alcoholic beverages during this past year." Explain what is meant by "alcoholic beverages" by using local examples of beer, wine, vodka, etc. Code answers in terms of "standard drinks". Place the correct answer number in the box at the right.

1. How often do you have a drink containing alcohol?

- (0) Never [Skip to Qs 9-10]
- (1) Monthly or less
- (2) 2 to 4 times a month
- (3) 2 to 3 times a week
- (4) 4 or more times a week

6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

2. How many drinks containing alcohol do you have on a typical day when you are drinking?

- (0) 1 or 2
- (1) 3 or 4
- (2) 5 or 6
- (3) 7, 8, or 9
- (4) 10 or more

7. How often during the last year have you had a feeling of guilt or remorse after drinking?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

3. How often do you have six or more drinks on one occasion?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

Skip to Questions 9 and 10 if Total Score for Questions 2 and 3 = 0

8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

4. How often during the last year have you found that you were not able to stop drinking once you had started?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

9. Have you or someone else been injured as a result of your drinking?

- (0) No
- (2) Yes, but not in the last year
- (4) Yes, during the last year

5. How often during the last year have you failed to do what was normally expected from you because of drinking?

- (0) Never
- (1) Less than monthly
- (2) Monthly
- (3) Weekly
- (4) Daily or almost daily

10. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?

- (0) No
- (2) Yes, but not in the last year
- (4) Yes, during the last year





Record total of specific items here

If total is greater than recommended cut-off, consult User's Manual.

The Alcohol Use Disorders Identification Test: Self-Report Version

PATIENT: Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest. Place an X in one box that best describes your answer to each question.

Questions	0	1	2	3	4	
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week	
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more	
3. How often do you have six or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
9. Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, during the last year	
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year	
					Total	

STANDARD DRINK EQUIVALENTS	APPROXIMATE NUMBER OF STANDARD DRINKS IN:
BEER or COOLER	
<p>12 oz.</p>  <p>~5% alcohol</p>	<p>12 oz. = 1 16 oz. = 1.3 22 oz. = 2 40 oz. = 3.3</p>
MALT LIQUOR	
<p>8-9 oz.</p>  <p>~7% alcohol</p>	<p>12 oz. = 1.5 16 oz. = 2 22 oz. = 2.5 40 oz. = 4.5</p>
TABLE WINE	
<p>5 oz.</p>  <p>~12% alcohol</p>	<p>a 750 mL (25 oz.) bottle = 5</p>
80-proof SPIRITS (hard liquor)	
<p>1.5 oz.</p>  <p>~40% alcohol</p>	<p>a mixed drink = 1 or more* a pint (16 oz.) = 11 a fifth (25 oz.) = 17 1.75 L (59 oz.) = 39</p> <p>*Note: Depending on factors such as the type of spirits and the recipe, one mixed drink can contain from one to three or more standard drinks.</p>

THE HAMILTON RATING SCALE FOR DEPRESSION

(to be administered by a health care professional)

Patient's Name _____

Date of Assessment _____

To rate the severity of depression in patients who are already diagnosed as depressed, administer this questionnaire. The higher the score, the more severe the depression.

For each item, write the correct number on the line next to the item. (Only one response per item)

1. DEPRESSED MOOD (Sadness, hopeless, helpless, worthless)

- _____ 0= Absent
1= These feeling states indicated only on questioning
2= These feeling states spontaneously reported verbally
3= Communicates feeling states non-verbally—i.e., through facial expression, posture, voice, and tendency to weep
4= Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication

2. FEELINGS OF GUILT

- _____ 0= Absent
1= Self reproach, feels he has let people down
2= Ideas of guilt or rumination over past errors or sinful deeds
3= Present illness is a punishment. Delusions of guilt
4= Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. SUICIDE

- _____ 0= Absent
1= Feels life is not worth living
2= Wishes he were dead or any thoughts of possible death to self
3= Suicidal ideas or gesture
4= Attempts at suicide (any serious attempt rates 4)

4. INSOMNIA EARLY

- _____ 0= No difficulty falling asleep
1= Complains of occasional difficulty falling asleep—i.e., more than 1/2 hour
2= Complains of nightly difficulty falling asleep

5. INSOMNIA MIDDLE

- _____ 0= No difficulty
1= Patient complains of being restless and disturbed during the night
2= Waking during the night—any getting out of bed rates 2 (except for purposes of voiding)

6. INSOMNIA LATE

_____ **0=** No difficulty

1= Waking in early hours of the morning but goes back to sleep

2= Unable to fall asleep again if he gets out of bed

7. WORK AND ACTIVITIES

_____ **0=** No difficulty

1= Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

2= Loss of interest in activity; hobbies or work—either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

3= Decrease in actual time spent in activities or decrease in productivity

4= Stopped working because of present illness

8. RETARDATION: PSYCHOMOTOR (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

_____ **0=** Normal speech and thought

1= Slight retardation at interview

2= Obvious retardation at interview

3= Interview difficult

4= Complete stupor

9. AGITATION

_____ **0=** None

1= Fidgetiness

2= Playing with hands, hair, etc.

3= Moving about, can't sit still

4= Hand wringing, nail biting, hair-pulling, biting of lips

10. ANXIETY (PSYCHOLOGICAL)

_____ **0=** No difficulty

1= Subjective tension and irritability

2= Worrying about minor matters

3= Apprehensive attitude apparent in face or speech

4= Fears expressed without questioning

11. ANXIETY SOMATIC: Physiological concomitants of anxiety, (i.e., effects of autonomic overactivity, "butterflies," indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (i.e., dry mouth, constipation)

_____ **0=** Absent

1= Mild

2= Moderate

3= Severe

4= Incapacitating

12. SOMATIC SYMPTOMS (GASTROINTESTINAL)

_____ 0= None

1= Loss of appetite but eating without encouragement from others. Food intake about normal

2= Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. SOMATIC SYMPTOMS GENERAL

_____ 0= None

1= Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability

2= Any clear-cut symptom rates 2

14. GENITAL SYMPTOMS (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

_____ 0= Absent

1= Mild

2= Severe

15. HYPOCHONDRIASIS

_____ 0= Not present

1= Self-absorption (bodily)

2= Preoccupation with health

3= Frequent complaints, requests for help, etc.

4= Hypochondriacal delusions

16. LOSS OF WEIGHT

_____ A. When rating by history:

0= No weight loss

1= Probably weight loss associated with present illness

2= Definite (according to patient) weight loss

3= Not assessed

17. INSIGHT

_____ 0= Acknowledges being depressed and ill

1= Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.

2= Denies being ill at all

18. DIURNAL VARIATION

_____ A. Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none

0= No variation

1= Worse in A.M.

2= Worse in P.M.

_____ B. When present, mark the severity of the variation. Mark "None" if NO variation

0= None

1= Mild

2= Severe

19. **DEPERSONALIZATION AND DEREALIZATION** (Such as: Feelings of unreality;
Nihilistic ideas)

- _____ 0= Absent
1= Mild
2= Moderate
3= Severe
4= Incapacitating

20. **PARANOID SYMPTOMS**

- _____ 0= None
1= Suspicious
2= Ideas of reference
3= Delusions of reference and persecution

21. **OBSessional AND COMPULSIVE SYMPTOMS**

- _____ 0= Absent
1= Mild
2= Severe

Total Score _____

Presented as a service by

GlaxoWellcome

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Research Triangle Park, NC 27709
Web site: www.glaxowellcome.com

Name: _____

Date: _____

Panic Disorder Severity Scale – Self Report Form

Several of the following questions refer to panic attacks and limited symptom attacks. For this questionnaire we define a panic attack as a sudden rush of fear or discomfort accompanied by at least 4 of the symptoms listed below. In order to qualify as a sudden rush, the symptoms must peak within 10 minutes. Episodes like panic attacks but having fewer than 4 of the listed symptoms are called limited symptom attacks. Here are the symptoms to count:

- | | | |
|-------------------------------|----------------------------|---|
| • Rapid or pounding heartbeat | • Chest pain or discomfort | • Chills or hot flushes |
| • Sweating | • Nausea | • Fear of losing control or going crazy |
| • Trembling or shaking | • Dizziness or faintness | • Fear of dying |
| • Breathlessness | • Feelings of unreality | |
| • Feeling of choking | • Numbness or tingling | |
-

1. How many panic and limited symptom attacks did you have during the week?
 - 0 No panic or limited symptom episodes
 - 1 Mild: no full panic attacks and no more than 1 limited symptom attack/day
 - 2 Moderate: 1 or 2 full panic attacks and/or multiple limited symptom attacks/day
 - 3 Severe: more than 2 full attacks but not more than 1/day on average
 - 4 Extreme: full panic attacks occurred more than once a day, more days than not

2. If you had any panic attacks during the past week, how distressing (uncomfortable, frightening) were they while they were happening? (If you had more than one, give an average rating. If you didn't have any panic attacks but did have limited symptom attacks, answer for the limited symptom attacks.)
 - 0 Not at all distressing, or no panic or limited symptom attacks during the past week
 - 1 Mildly distressing (not too intense)
 - 2 Moderately distressing (intense, but still manageable)
 - 3 Severely distressing (very intense)
 - 4 Extremely distressing (extreme distress during all attacks)

3. During the past week, how much have you worried or felt anxious about when your next panic attack would occur or about fears related to the attacks (for example, that they could mean you have physical or mental health problems or could cause you social embarrassment)?
 - 0 Not at all
 - 1 Occasionally or only mildly
 - 2 Frequently or moderately
 - 3 Very often or to a very disturbing degree
 - 4 Nearly constantly and to a disabling extent

4. During the past week were there any places or situations (e.g., public transportation, movie theaters, crowds, bridges, tunnels, shopping malls, being alone) you avoided, or felt afraid of (uncomfortable in, wanted to avoid or leave), because of fear of having a panic attack? Are there any other situations that you would have avoided or been afraid of if they had come up during the week, for the same reason? If yes to either question, please rate your level of fear and avoidance this past week.
 - 0 None: no fear or avoidance
 - 1 Mild: occasional fear and/or avoidance but I could usually confront or endure the situation. There was little or no modification of my lifestyle due to this.
 - 2 Moderate: noticeable fear and/or avoidance but still manageable. I avoided some situations, but I could confront them with a companion. There was some modification of my lifestyle because of this, but my overall functioning was not impaired.
 - 3 Severe: extensive avoidance. Substantial modification of my lifestyle was required to accommodate the avoidance making it difficult to manage usual activities.
 - 4 Extreme: pervasive disabling fear and/or avoidance. Extensive modification in my lifestyle was required such that important tasks were not performed.

5. During the past week, were there any activities (e.g., physical exertion, sexual relations, taking a hot shower or bath, drinking coffee, watching an exciting or scary movie) that you avoided, or felt afraid of (uncomfortable doing, wanted to avoid or stop), because they caused physical sensations like those you feel during panic attacks or that you were afraid might trigger a panic attack? Are there any other activities that you would have avoided or been afraid of if they had come up during the week for that reason? If yes to either question, please rate your level of fear and avoidance of those activities this past week.
- 0 No fear or avoidance of situations or activities because of distressing physical sensations
 - 1 Mild: occasional fear and/or avoidance, but usually I could confront or endure with little distress activities that cause physical sensations. There was little modification of my lifestyle due to this.
 - 2 Moderate: noticeable avoidance but still manageable. There was definite, but limited, modification of my lifestyle such that my overall functioning was not impaired.
 - 3 Severe: extensive avoidance. There was substantial modification of my lifestyle or interference in my functioning.
 - 4 Extreme: pervasive and disabling avoidance. There was extensive modification in my lifestyle due to this such that important tasks or activities were not performed.
6. During the past week, how much did the above symptoms altogether (panic and limited symptom attacks, worry about attacks, and fear of situations and activities because of attacks) interfere with your ability to work or carry out your responsibilities at home? (If your work or home responsibilities were less than usual this past week, answer how you think you would have done if the responsibilities had been usual.)
- 0 No interference with work or home responsibilities
 - 1 Slight interference with work or home responsibilities, but I could do nearly everything I could if I didn't have these problems.
 - 2 Significant interference with work or home responsibilities, but I still could manage to do the things I needed to do.
 - 3 Substantial impairment in work or home responsibilities; there were many important things I couldn't do because of these problems.
 - 4 Extreme, incapacitating impairment such that I was essentially unable to manage any work or home responsibilities.
7. During the past week, how much did panic and limited symptom attacks, worry about attacks and fear of situations and activities because of attacks interfere with your social life? (If you didn't have many opportunities to socialize this past week, answer how you think you would have done if you did have opportunities.)
- 0 No interference
 - 1 Slight interference with social activities, but I could do nearly everything I could if I didn't have these problems.
 - 2 Significant interference with social activities but I could manage to do most things if I made the effort.
 - 3 Substantial impairment in social activities; there are many social things I couldn't do because of these problems.
 - 4 Extreme, incapacitating impairment, such that there was hardly anything social I could do.

Scoring the Panic Disorder Severity Scale

In scoring the Panic Disorder Severity Scale, items are rated on a scale of 0 to 4. A composite score is established by averaging the scores of the seven items. The table below can be used to convert raw scores (sum of individual item scores) into composite scores.

Raw Score	Composite Score	Raw Score	Composite Score	Raw Score	Composite Score	Raw Score	Composite Score
0	0	7	1.00	14	2.00	21	3.00
1	.14	8	1.14	15	2.14	22	3.14
2	.28	9	1.28	16	2.28	23	3.28
3	.42	10	1.42	17	2.42	24	3.42
4	.57	11	1.57	18	2.57	25	3.57
5	.71	12	1.71	19	2.71	26	3.71
6	.85	13	1.85	20	2.85	27	3.85
						28	4.00

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Citation: Shear MK, Brown TA, Barlow DH, Money R, Sholomskas DE, Woods SW, Gorman JM, Papp LA. Multicenter collaborative Panic Disorder Severity Scale. American Journal of Psychiatry 1997;154:1571-1575

Five Factor Model Rating Form

Please describe yourself on a 1-5 scale on each of the following 30 personality traits, where 1 is extremely low (i.e., extremely lower than the average person), 2 is low, 3 is neither high nor low (i.e., does not differ from the average person), 4 is high and 5 is extremely high. Use any number from 1 to 5. Please provide a rating for all 30 traits.

For example on the first trait (anxiousness), a score of 1 would indicate that you think you are extremely low in anxiousness (i.e., relaxed, unconcerned, cool). A score of 2 would indicate that you think you are low in anxiousness (lower than the average person, but not extremely low). A score of 3 would indicate that you think you are neither high nor low in anxiousness (does not differ from the average person) or that you are unable to decide. Circle the number that applies to the individual for each of the 30 traits.

5= Extremely high 4= High 3= Neither high nor low 2= Low 1=Extremely Low

1. Anxiousness (fearful, apprehensive)	5	4	3	2	1	(relaxed, unconcerned, cool)
2. Angry hostility (angry, bitter)	5	4	3	2	1	(even-tempered)
3. Depressiveness (pessimistic, glum)	5	4	3	2	1	(optimistic)
4. Self-consciousness (timid, embarrassed)	5	4	3	2	1	(self-assured, glib, shameless)
5. Impulsivity (tempted, urgency)	5	4	3	2	1	(controlled, restrained)
6. Vulnerability (helpless, fragile)	5	4	3	2	1	(clear-thinking, fearless, unflappable)
7. Warmth (cordial, affectionate, attached)	5	4	3	2	1	(cold, aloof, indifferent)
8. Gregariousness (sociable, outgoing)	5	4	3	2	1	(withdrawn, isolated)
9. Assertiveness (dominant, forceful)	5	4	3	2	1	(unassuming, quiet, resigned)
10. Activity (vigorous, energetic, active)	5	4	3	2	1	(passive, lethargic)
11. Excitement-seeking (reckless, daring)	5	4	3	2	1	(cautious, monotonous, dull)
12. Positive emotions (high-spirited)	5	4	3	2	1	(placid, anhedonic)
13. Fantasy (dreamer, unrealistic, imaginative)	5	4	3	2	1	(practical, concrete)
14. Aesthetics (aberrant interests, aesthetic)	5	4	3	2	1	(uninvolved, no aesthetic interests)
15. Feelings (self-aware)	5	4	3	2	1	(constricted, unaware, alexythymic)
16. Actions (unconventional, eccentric)	5	4	3	2	1	(routine, predictable, habitual, stubborn)
17. Ideas (strange, odd, peculiar, creative)	5	4	3	2	1	(pragmatic, rigid)
18. Values (permissive, broad-minded)	5	4	3	2	1	(traditional, inflexible, dogmatic)
19. Trust (gullible, naïve, trusting)	5	4	3	2	1	(skeptical, cynical, suspicious, paranoid)
20. Straightforwardness (confiding, honest)	5	4	3	2	1	(cunning, manipulative, deceptive)
21. Altruism (sacrificial, giving)	5	4	3	2	1	(stingy, selfish, greedy, exploitative)
22. Compliance (docile, cooperative)	5	4	3	2	1	(oppositional, combative, aggressive)
23. Modesty (meek, self-effacing, humble)	5	4	3	2	1	(confident, boastful, arrogant)
24. Tender-mindedness (soft, empathetic)	5	4	3	2	1	(tough, callous, ruthless)
25. Competence (perfectionistic, efficient)	5	4	3	2	1	(lax, negligent)
26. Order (ordered, methodical, organized)	5	4	3	2	1	(haphazard, disorganized, sloppy)
27. Dutifulness (rigid, reliable, dependable)	5	4	3	2	1	(casual, undependable, unethical)
28. Achievement (workaholic, ambitious)	5	4	3	2	1	(aimless, desultory)
29. Self-discipline (dogged, devoted)	5	4	3	2	1	(hedonistic, negligent)
30. Deliberation (cautious, ruminative, reflective)	5	4	3	2	1	(hasty, careless, rash)

Young Mania Rating Scale (YMRS)

Guide for Scoring Items – The purpose of each item is to rate the severity of that abnormality in the patient. When several keys are given for a particular grade of severity, the presence of only one is required to qualify for that rating.

The keys provided are guides. One can ignore the keys if that is necessary to indicate severity, although this should be the exception rather than the rule.

Scoring between the points given (whole or half points) is possible and encouraged after experience with the scale is acquired. This is particularly useful when severity of a particular item in a patient does not follow the progression indicated by the keys.

1. *Elevated Mood*

- 0 Absent
- 1 Mildly or possibly increased on questioning
- 2 Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content
- 3 Elevated, inappropriate to content; humorous
- 4 Euphoric; inappropriate to content; singing

2. *Increased Motor Activity – Energy*

- 0 Absent
- 1 Subjectively increased
- 2 Animated; gestures increased
- 3 Excessive energy; hyperactive at times; restless (can be calmed)
- 4 Motor excitement; continuous hyperactivity (cannot be calmed)

3. *Sexual Interest*

- 0 Normal; not increased
- 1 Mildly or possibly increased
- 2 Definitive subjective increase on questioning
- 3 Spontaneous sexual content; elaborates on sexual matters; hypersexual by self-report
- 4 Overt sexual acts (towards patients, staff, or interviewer)

4. *Sleep*

- 0 Reports no decrease in sleep
- 1 Sleeping less than normal amount by up to one hour
- 2 Sleeping less than normal by more than one hour
- 3 Reports decreased need for sleep
- 4 Denies need for sleep

5. *Irritability*

- 0 Absent
- 2 Subjectively increased
- 4 Irritable at times during interview; recent episodes of anger or annoyance on ward
- 6 Frequently irritable during interview; short, curt throughout
- 8 Hostile, uncooperative; interview impossible

6. *Speech (Rate and Amount)*

- 0 No increase
- 2 Feels talkative
- 4 Increased rate or amount at times, verbose at times
- 6 Push; consistently increased rate and amount; difficult to interrupt
- 8 Pressured; uninterruptible, continuous speech

7. *Language – Thought Disorder*

- 0 Absent
- 1 Circumstantial; mild distractibility; quick thoughts
- 2 Distractible; loses goal of thought; changes topics frequently; racing thoughts
- 3 Flight of ideas; tangentiality; difficult to follow; rhyming; echolalia
- 4 Incoherent; communication impossible

8. *Content*

- 0 Normal
- 2 Questionable plans, new interests
- 4 Special project(s); hyperreligious
- 6 Grandiose or paranoid ideas; ideas of reference
- 8 Delusions; hallucinations

9. *Disruptive – Aggressive Behavior*

- 0 Absent; cooperative
- 2 Sarcastic; loud at times; guarded
- 4 Demanding; threats on ward
- 6 Threatens interviewer; shouting; interview difficult
- 8 Assaultive; destructive; interview impossible

10. *Appearance*

- 0 Appropriate dress and grooming
- 1 Minimally unkempt
- 2 Poorly groomed; moderately disheveled; overdressed
- 3 Disheveled; partly clothed; garish makeup
- 4 Completely unkempt; decorated; bizarre garb

11. *Insight*

- 0 Present; admits illness; agrees with need for treatment
- 1 Possibly ill
- 2 Admits behavior change, but denies illness
- 3 Admits possible change in behavior, but denies illness
- 4 Denies any behavior changes

Name: _____

Rater: _____

Date: _____

Score: _____

KUMAR	42	M	10	<2	NSKNAGAR	W	H	12	6	3	N	0	N	SKIN ERU	N	N	N	24	0	5	0	0	0	0	6	3	FELTGO	0	0	ADS	5	2	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
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